

US3382035 (Prod: Advanced Clinical Research – Be Well MD - ERN - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:40:51

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US3382035

Form: Participant Creation

Data signed: (b) (4) 26 Jan 2021 16:57:58

Generated On: 11 Aug 2021 22:40:51

[Participant ID](#)

US3382035

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

US3382035

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Date of Birth (MMM yyyy)	(b) (6) 1988
Age	32
Age Units	YEARS
Age (Derived)	32
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) 26 Jan 2021 16:58:09

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Jan 2021 16:58:09

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Jan 2021 16:58:09

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Jan 2021 16:58:09

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Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Jan 2021 16:58:09

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Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Jan 2021 16:58:09

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Condition	HERPES SIMPLEX VIRUS 2
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 16:58:10

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:38 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:38
Height (xxx.x)	73.5 in
Weight (xxx.x)	234.9 lb
BMI (xxx.x)	30.63502 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 16:58:09

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 16:58:09

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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) 26 Jan 2021 16:58:09

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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) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 103882

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 16:58:10

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:38 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:38
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	14:13 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 14:13
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 13:40 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 13:40

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

13:13 (24 HR)

Collection date and time (derived)

14 AUG 2020 13:13

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:27	14 AUG 2020 13:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 14:18

PC Open Date & Time

14 AUG 2020 14:00

PC Close Date & Time

14 AUG 2020 16:30

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp	14 AUG 2020 20:38
PC Open Date & Time	14 AUG 2020 17:25
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

15 AUG 2020 12:23

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 13:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:13

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 14:26

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:40:51

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 12:07

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:40:51

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

98.6 °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

20 AUG 2020 12:03

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

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

14 AUG 2020 14:19

PC Open Date & Time

14 AUG 2020 14:00

PC Close Date & Time

14 AUG 2020 16:30

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

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

40

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 20:40

PC Open Date & Time

14 AUG 2020 17:25

PC Close Date & Time

15 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

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

30

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:24

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:40:51

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

16 AUG 2020 12:02

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:40:51

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

17 AUG 2020 12:13

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:40:51

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

18 AUG 2020 14:27

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:40:51

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

19 AUG 2020 12:04

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input type="radio"/>
Please select one response below	Does not interfere with activity <input checked="" type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input type="radio"/>
Please select one response below	Does not interfere with activity <input checked="" type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	20 AUG 2020 12:01
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 14:19
PC Open Date & Time	14 AUG 2020 14:00
PC Close Date & Time	14 AUG 2020 16:30

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 20:41
PC Open Date & Time	14 AUG 2020 17:25
PC Close Date & Time	15 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

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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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:25
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

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 ☒

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:02
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

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 ☒

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 12:14
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

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 ☒

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 14:27
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

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 ☒

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:04
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

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 ☒

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 21 AUG 2020 12:30

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp 22 AUG 2020 12:05

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 10

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 ☐

PC Time Stamp 23 AUG 2020 12:04

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 11

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 ☐

PC Time Stamp 24 AUG 2020 12:33

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 21 AUG 2020 12:30

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

21 AUG 2020 12:30

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 22 AUG 2020 12:05

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 AUG 2020 12:30

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp	22 AUG 2020 12:05
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PC Open Date & Time	22 AUG 2020 12:00
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PC Close Date & Time	23 AUG 2020 11:59
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US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 10

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 AUG 2020 12:04

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 11

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 AUG 2020 12:33

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 12:30
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 AUG 2020 12:05
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 12:04
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 11

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

No ☐

Yes ☒

PC Time stamp

24 AUG 2020 12:33

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 8

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 21 AUG 2020 12:30

PC Open Date and Time 21 AUG 2020 12:00

PC Close Date and Time 22 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 9

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 22 AUG 2020 12:05

PC Open Date and Time 22 AUG 2020 12:00

PC Close Date and Time 23 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 10

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:04

PC Open Date and Time

23 AUG 2020 12:00

PC Close Date and Time

24 AUG 2020 11:59

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 11

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 24 AUG 2020 12:33

PC Open Date and Time 24 AUG 2020 12:00

PC Close Date and Time 25 AUG 2020 11:59

US3382035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:48:10

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

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	

US3382035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

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?

US3382035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

11 SEP 2020 10:40

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	11 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

US3382035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	VISIT3

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 11:24
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3382035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

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.

US3382035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 OCT 2020

Collection time (00:00-23:59)

11:51 (24 HR)

Collection date and time (derived)

09 OCT 2020 11:51

US3382035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:10

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 OCT 2020 13:17:16
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 00:05:43

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 78

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

No ☒

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 OCT 2020 00:11:11

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 00:01:29
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 99
Have you 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"/>

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 NOV 2020 16:03:29

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 22:39:36
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 02:34:36

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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	13 DEC 2020 00:04:54
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

20 DEC 2020 00:02:46

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

31 DEC 2020 14:28:30

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 16:52:10
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

13 JAN 2021 12:03:02

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

17 JAN 2021 11:21:53

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 12:20:17
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	31 JAN 2021 00:18:49
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 FEB 2021 13:24:09
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 FEB 2021 03:03:35
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 08:35:01
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 FEB 2021 00:02:34
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 15:54:26

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 11:04:06
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☒

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

30 MAR 2021 11:27:12

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	04 APR 2021 01:12:34
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 12:19:17

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 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 APR 2021 09:11:15
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 APR 2021 07:38:35

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 13:10:48

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 <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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 <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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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°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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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="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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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°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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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10 FEB 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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13 FEB 2022 00:01

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17 FEB 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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°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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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06 MAR 2022 00:01

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10 MAR 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

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13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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20 MAR 2022 00:01

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24 MAR 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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31 MAR 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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03 APR 2022 00:01

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07 APR 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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10 APR 2022 00:01

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14 APR 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 649

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

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

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

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

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

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

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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°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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:40:51

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 00:02:17

US3382035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:17:59

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:17:59

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:17:59

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:17:59

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

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

Visit date (dd MMM yyyy)	12 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 19:58:20

Generated On: 11 Aug 2021 22:40:51

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) _____

US3382035

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

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.

US3382035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 MAR 2021

Collection time (00:00-23:59)

11:38 (24 HR)

Collection date and time (derived)

12 MAR 2021 11:38

US3382035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted? Yes ☐
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Mar 2021 15:48:10

Generated On: 11 Aug 2021 22:40:51

Date of Contact	22 AUG 2020
Time of Contact	15:18
Date and Time of Contact (derived)	22 AUG 2020 15:18
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

Date	24 AUG 2020
------	-------------

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

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

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

Temperature	97.9 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

Date	25 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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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US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

Date	26 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

Date	27 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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)

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Generated On: 11 Aug 2021 22:40:51

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

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

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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)

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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	28 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input 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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Form: Symptom Log (5)

Data signed: (b) (4) 08 Apr 2021 22:54:38

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

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Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 22:54:38

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Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

Date	29 AUG 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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

Data signed: (b) (4) 08 Apr 2021 22:54:38

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

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Form: Symptom Log (7)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input 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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Form: Symptom Log (7)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

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Form: Symptom Log (8)

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Symptom Day

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

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Form: Symptom Log (8)

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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	31 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Generated On: 11 Aug 2021 22:40:51

	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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Form: Symptom Log (8)

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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 22 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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 22 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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 22 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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	02 SEP 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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 22 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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 type="radio"/>
	Mild	<input checked="" 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 22 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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 22 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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	03 SEP 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.2 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 22 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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 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"/>

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 14 Apr 2021 18:03:20

Generated On: 11 Aug 2021 22:40:51

Date of Visit	24 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	24 AUG 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)	1

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 31 Mar 2021 19:57:23

Generated On: 11 Aug 2021 22:40:51

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 31 Mar 2021 19:57:23

Generated On: 11 Aug 2021 22:40:51

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

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 31 Mar 2021 19:57:23

Generated On: 11 Aug 2021 22:40:51

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 31 Mar 2021 19:57:23

Generated On: 11 Aug 2021 22:40:51

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Mar 2021 15:48:10

Generated On: 11 Aug 2021 22:40:51

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	26 AUG 2020
Day 5	Yes	28 AUG 2020
Day 7	Yes	30 AUG 2020
Day 9	Yes	01 SEP 2020
Day 14	Yes	06 SEP 2020
Day 21	Yes	13 SEP 2020
Day 28	NA (COVID-19 Negative)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

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) _____

Height (xxx.x) _____

Weight (xxx.x) _____

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) _____

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

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: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Jan 2021 16:57:59

Generated On: 11 Aug 2021 22:40:51

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

24 AUG 2020

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

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 SICKD28

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 19:57:23

Generated On: 11 Aug 2021 22:40:51

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) _____

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 19:57:23

Generated On: 11 Aug 2021 22:40:51

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 31 Mar 2021 19:57:23

Generated On: 11 Aug 2021 22:40:51

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3382035

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

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

Visit date (dd MMM yyyy)	29 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3382035

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:48:10

Generated On: 11 Aug 2021 22:40:51

Date of updated informed consent (<i>dd MMM yyyy</i>)	29 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	29 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3382035

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

Height	73.75 in
Weight	249.4 lb
BMI (xxx.x)	32.30593

US3382035

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

Height	73.75 in
Weight	249.4 lb
BMI (xxx.x)	32.30593
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)	29 JAN 2021
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 10:34
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3382035

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

Height	73.75 in
Weight	249.4 lb
BMI (xxx.x)	32.30593
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)	29 JAN 2021
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 11:48
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3382035

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

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.

US3382035

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

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) 29 JAN 2021

What was the treatment time? (00:00-23:59) 11:16 (24 HR)

Treatment Date and Time (derived) 29 JAN 2021 11:16

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

US3382035

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

10:44 (24 HR)

Collection date and time (derived)

29 JAN 2021 10:44

US3382035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Mar 2021 15:48:10

Generated On: 11 Aug 2021 22:40:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3382035

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:17:59

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:17:59

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:28
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

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)	26 FEB 2021
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 12:20
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3382035

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

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.

US3382035

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

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) 26 FEB 2021

What was the treatment time? (00:00-23:59) 11:46 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 11:46

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

US3382035

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382035

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:41:07

Generated On: 11 Aug 2021 22:40:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382035

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 22:54:39

Generated On: 11 Aug 2021 22:40:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 22:54:39

Generated On: 11 Aug 2021 22:40:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 11:34
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3382035

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 22:54:39

Generated On: 11 Aug 2021 22:40:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3382035

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 22:54:39

Generated On: 11 Aug 2021 22:40:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	12:07 (24 HR)
Collection date and time (derived)	30 MAR 2021 12:07

US3382035

Folder: Unscheduled (1)

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:40:51

Visit Date

Please check all assessments that apply for this visit

Physical Exam

Vital Signs

Immunogenicity Assessment

Pregnancy Test

US3382035

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Jan 2021 16:57:58

Generated On: 11 Aug 2021 22:40:51

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3382035

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

AEID

Adverse event

COVID-19 [POSITIVE TEST]

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)

14 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3382035

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

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	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)	

US3382035

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

AEID

Adverse event

PRODUCTIVE COUGH

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)

12 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

389 of 2679

EAB) (1725)

US3382035

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

AEID

Adverse event

INJECTION SITE PAIN

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)

16 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

AEID

Adverse event

FATIGUE

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)

17 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

393 of 2679

EAB) (1725)

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

AEID

Adverse event

MUSCLE ACHE

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)

19 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

AEID

Adverse event

UNDERARM GLAND SWELLING

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)

16 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

AEID

Adverse event

HEADACHE

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)

20 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 03:16:23

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Jan 2021 16:57:58

Generated On: 11 Aug 2021 22:40:51

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 100

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) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication EXCEDRIN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 2

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 (2)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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 2002	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication TRUVADA

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR HIV

Dose per administration 200/300

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 (3)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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 (4)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication GLUCOSAMINE CHONDROITIN

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1500/1200

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) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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 2012	
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 (6)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 150

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 (6)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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 2012	
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 (7)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication ZINC

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (8)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication VITAMIN B12

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

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 (8)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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 2012	
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"/>

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication VALTREX

Prophylaxis Yes ☐
No ☒

Indication HERPES SIMPLEX VIRUS 2

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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"/>

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR BLOOD
CLOTS RELATED TO COVID-19

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

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

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	FLU
------------	-----

Dose per administration	0.5
-------------------------	-----

Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input type="radio"/>
	unknown <input type="radio"/>
	other <input checked="" type="radio"/>

If frequency is Other, specify

ONCE EVER YEAR

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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)		29 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 JAN 2021		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SOLICITED SYMPTOMS OF
INJECTION SITE SORENESS
AND HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SOLICITED SYMPTOMS OF
INJECTION SITE SORENESS
AND HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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)	27 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 FEB 2021
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"/>

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

Name of Medication BENZONATATE

Prophylaxis Yes ☐
No ☒

Indication PRODUCTIVE COUGH

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 22:54:38

Generated On: 11 Aug 2021 22:40:51

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 15 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3382035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3382035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 17:17:58

Generated On: 11 Aug 2021 22:40:51

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 AUG 2020	COVID PCR TEST	Diagnostic	

US3382035

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Jan 2021 16:57:59

Generated On: 11 Aug 2021 22:40:51

Date of dosing discontinuation (dd MMM yyyy) 24 AUG 2020

Primary reason for dosing discontinuation

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

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

US3382035

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:40:51

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 ☐

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

SAEID	USA-US096-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Jan 2021 16:58:09

Generated On: 11 Aug 2021 22:40:51

SAEID	USA-US096-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	29/SEP/2020 15:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3382035 (Prod: Advanced Clinical Research – Be Well MD - ERN - PPDS)

US3382035

Form: Participant Creation

Generated On: 11 Aug 2021 22:40:51

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'US3382035'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	14 Aug 2020 17:09:27

US3382035

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:05:37
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:11

US3382035

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:05:37
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	14 Aug 2020 17:09:28

US3382035

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:05:37
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Clinic (Clinic)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:11

US3382035

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'SCRN'	System	14 Aug 2020 18:28:11

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered (b) (6) 1988'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	14 Aug 2020 17:09:29

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '32'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'YEARS'	System	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered '32'	System	14 Aug 2020 18:28:50

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Male (M)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'l'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:51

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:06:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:30

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:07:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 Aug 2020'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:50

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'Aug 2020'	System	14 Aug 2020 18:28:50

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered '2020'	System	14 Aug 2020 18:28:50

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:07:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Amendment 2 (2)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:50

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:07:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:50

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:07:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:50

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:07:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:50

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:07:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:50

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:07:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	14 Aug 2020 17:09:28

US3382035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:51

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'I'	System	14 Aug 2020 18:28:54

US3382035

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:40:51

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:07:25
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:28:54

US3382035

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:40:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
DataPoint Verified.		15 Apr 2021 19:07:32
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:52:25

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Aug 2020 18:57:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 18:57:27
Data point term sent to Coder	System	15 Aug 2020 18:56:32
User entered 'MIGRAINE HEADACHES'	Dana Finley (b) (4)	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'UN UNK 2002'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'Jan 2002'	System	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered '2002'	System	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered empty.	System	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered empty.	System	15 Aug 2020 18:56:18

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 18:58:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 18:58:28
Data point term sent to Coder	System	15 Aug 2020 18:57:33
User entered 'ANXIETY'	Dana Finley (b) (4)	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'UN UNK 2016'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'Jan 2016'	System	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered '2016'	System	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered empty.	System	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered empty.	System	15 Aug 2020 18:56:42

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 18:58:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 18:58:28
Data point term sent to Coder	System	15 Aug 2020 18:57:34
User entered 'SEASONAL ALLERGIES'	Dana Finley (b) (4)	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'UN UNK 2012'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'Jan 2012'	System	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered '2012'	System	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered empty.	System	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered empty.	System	15 Aug 2020 18:57:32

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type II - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 19:00:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 19:00:14
Data point term sent to Coder	System	15 Aug 2020 18:58:39
User entered 'HERPES SIMPLEX VIRUS 2'	Dana Finley (b) (4)	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'UN UNK 2014'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'Jan 2014'	System	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered '2014'	System	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered empty.	System	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered empty.	System	15 Aug 2020 18:58:05

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 Aug 2020'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '12:38'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered '14 Aug 2020 12:38'	System	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Aug 2020 18:55:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 18:55:11
User entered '73.5' in reason for change: Data Entry Error	Dana Finley (b) (4)	15 Aug 2020 18:55:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Aug 2020 18:54:41
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 18:54:41
DataPoint set to visible.	(b) (4) System	14 Aug 2020 18:28:54

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Aug 2020 18:55:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 18:55:11
User entered '234.9' lb reason for change: Data Entry Dana Finley Error	(b) (4) (b) (4)	15 Aug 2020 18:55:11
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 18:54:41
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 18:54:41
DataPoint set to visible.	System	14 Aug 2020 18:28:54

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
Amendment Manager: User entered '30.63502'	System	16 Sep 2020 23:57:31
User entered '30.6'	System	15 Aug 2020 18:55:11
User entered empty.	System	15 Aug 2020 18:54:41
DataPoint set to visible.	System	14 Aug 2020 18:28:54

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'kg/m2'	System	15 Aug 2020 18:55:11
User entered empty.	System	15 Aug 2020 18:54:41
DataPoint set to visible.	System	14 Aug 2020 18:28:54

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:52:00
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' answered with 'updated' (Site from DM).	Robin Dotson (b) (4) (b) (4)	24 Sep 2020 22:50:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Robin Dotson (b) (4) (b) (4)	24 Sep 2020 22:50:04
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:44:02
User entered '98.2' F	Dana Finley (b) (4)	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty; reason for change Data Entry Error	(b) (4)	
	Robin Dotson (b) (4)	24 Sep 2020 22:50:04
User entered 'Oral (Oral)'	(b) (4)	
	Dana Finley (b) (4)	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 22:50:04
User entered '59'	Robin Dotson (b) (4)	15 Aug 2020 18:54:41
	Dana Finley (b) (4)	

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'bpm'	System	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 22:50:04
User entered '16'	Robin Dotson (b) (4)	15 Aug 2020 18:54:41
	Dana Finley (b) (4)	

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'breaths/min'	System	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 22:50:04
User entered '128'	Robin Dotson (b) (4)	15 Aug 2020 18:54:41
	Dana Finley (b) (4)	

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'mmHg'	System	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 22:50:04
User entered '80'	Robin Dotson (b) (4)	15 Aug 2020 18:54:41
	Dana Finley (b) (4)	

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User entered 'mmHg'	System	15 Aug 2020 18:54:41

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03

US3382035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03

US3382035

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:55:23

US3382035

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 Aug 2020'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:55:23

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'I'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '0'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:29:42

US3382035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:30:16

US3382035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 Aug 2020'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:30:16

US3382035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[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 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Clinic (Clinic)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:30:16

US3382035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'VISIT1'	System	14 Aug 2020 18:30:16

US3382035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	14 Aug 2020 18:19:34

US3382035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:51

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 04:36:05
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:36:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 18:19:34
User entered '103882' (non-conformant).	RWS_ENDPOINT ENDPOINT(b) (4)	14 Aug 2020 18:19:34

US3382035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:51

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	14 Aug 2020 18:19:34

US3382035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:51

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 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:30:29

US3382035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:51

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 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:30:29

US3382035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:51

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:30:29

US3382035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:51

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:30:29

US3382035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:30:29

US3382035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:51

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4)	24 Sep 2020 21:27:49
Amendment Manager: DataPoint set to visible.	Sikhongi Phungwayo	19 Sep 2020 10:21:12
Amendment Manager inserted this DataPoint.	(b) (4)	19 Sep 2020 07:20:12
	System	19 Sep 2020 10:21:12
	System	19 Sep 2020 07:20:12

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:52:13
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Robin Dotson (b) (4) (b) (4)	24 Sep 2020 22:50:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Robin Dotson (b) (4) (b) (4)	24 Sep 2020 22:50:33
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:42:56
User entered '73.5' in	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 22:50:33
User entered '234.9' lb	Robin Dotson (b) (4)	14 Aug 2020 18:53:47
	Dana Finley (b) (4)	

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:52:13
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Robin Dotson (b) (4) (b) (4)	24 Sep 2020 22:50:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Robin Dotson (b) (4) (b) (4)	24 Sep 2020 22:50:33
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:42:56
User entered '73.5' in	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 22:50:33
User entered '234.9' lb	Robin Dotson (b) (4)	14 Aug 2020 18:53:47
	Dana Finley (b) (4)	

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User accepted default value 'Pre-Dose (PREDOSE)'	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 Aug 2020'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '12:38'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered '14 Aug 2020 12:38'	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '98.2' F	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Oral (Oral)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '59'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'bpm'	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '16'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'breaths/min'	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '128'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'mmHg'	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '80'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'mmHg'	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:52:13
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Robin Dotson (b) (4) (b) (4)	24 Sep 2020 22:50:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Robin Dotson (b) (4) (b) (4)	24 Sep 2020 22:50:33
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:42:56
User entered '73.5' in	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 22:50:33
User entered '234.9' lb	Robin Dotson (b) (4)	14 Aug 2020 18:53:47
	Dana Finley (b) (4)	

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User accepted default value 'Post-Dose (POSTDOSE)'	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 19:16:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Dana Finley (b) (4)	14 Aug 2020 19:16:38
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 18:53:47
User entered empty.	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4)	14 Aug 2020 19:16:38
User entered empty.	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 07:34:37
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 19:16:38
User entered '14:13' reason for change: Data Entry Error	Dana Finley (b) (4)	14 Aug 2020 19:16:38
User entered empty.	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered '14 Aug 2020 14:13'	System	14 Aug 2020 19:16:38
User entered empty.	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '98.8' F reason for change: Data Entry Error	(b) (4)	14 Aug 2020 19:16:38
User entered empty.	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	14 Aug 2020 19:16:38
User entered empty.	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '54' reason for change: Data Entry Error	(b) (4)	14 Aug 2020 19:16:38
User entered empty.	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'bpm'	System	14 Aug 2020 19:16:38
User entered empty.	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '16' reason for change: Data Entry Error	(b) (4)	14 Aug 2020 19:16:38
User entered empty.	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'breaths/min'	System	14 Aug 2020 19:16:38
User entered empty.	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '122' reason for change: Data Entry Error	(b) (4)	14 Aug 2020 19:16:38
User entered empty.	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'mmHg'	System	14 Aug 2020 19:16:38
User entered empty.	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '81' reason for change: Data Entry Error	(b) (4)	14 Aug 2020 19:16:38
User entered empty.	Dana Finley (b) (4)	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'mmHg'	System	14 Aug 2020 19:16:38
User entered empty.	System	14 Aug 2020 18:53:47

US3382035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Triny Cooper (b) (4)	19 Oct 2020 23:18:09
User entered 'Yes (Y)'	Dana Finley (b) (4)	14 Aug 2020 18:45:25

US3382035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty; reason for change Data Entry Error	(b) (4)	
	Triny Cooper (b) (4)	19 Oct 2020 23:18:09
User entered '14 Aug 2020'	Dana Finley (b) (4)	14 Aug 2020 18:45:25

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

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 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 Aug 2020'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '13:40'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered '14 Aug 2020 13:40'	System	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'ONCE'	System	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 18:44:58

US3382035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:56:25

US3382035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 Aug 2020'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:56:25

US3382035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '13:13'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:56:25

US3382035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered '14 Aug 2020 13:13'	System	14 Aug 2020 18:56:25

US3382035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:40:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '14 Aug 2020'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:57:04

US3382035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dana Finley (b) (4)	14 Aug 2020 18:57:04

US3382035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:57:04

US3382035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '13:27'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:57:04

US3382035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered '14 Aug 2020 13:27'	System	14 Aug 2020 18:57:04

US3382035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dana Finley (b) (4)	14 Aug 2020 18:57:04

US3382035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:57:04

US3382035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:57:04

US3382035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered empty.	System	14 Aug 2020 18:57:04

US3382035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	14 Aug 2020 18:57:26

US3382035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'I'	System	14 Aug 2020 18:57:26

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:18:15', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'fdd335d4-3cf2-45d9-a531-66afd40d4c41'	System	14 Aug 2020 19:18:30
User entered 'Yes (Y)'	System	14 Aug 2020 19:18:30

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:18:20', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'fdd335d4-3cf2-45d9-a531-66afd40d4c41'	System	14 Aug 2020 19:18:30
User entered '98.8'	System	14 Aug 2020 19:18:30

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:18:23', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'fdd335d4-3cf2-45d9-a531-66afd40d4c41'	System	14 Aug 2020 19:18:30
User entered 'No (N)'	System	14 Aug 2020 19:18:30

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:18:28', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'fdd335d4-3cf2-45d9-a531-66afd40d4c41'	System	14 Aug 2020 19:18:30
User entered '14 Aug 2020 14:18'	System	14 Aug 2020 19:18:30

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '14 Aug 2020 14:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '14 Aug 2020 16:30'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:38:37', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1fe483d0-2b84-42a6-a558-670db8c72be9'	System	15 Aug 2020 01:38:48
User entered 'Yes (Y)'	System	15 Aug 2020 01:38:48

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:38:40', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1fe483d0-2b84-42a6-a558-670db8c72be9'	System	15 Aug 2020 01:38:48
User entered '98.5'	System	15 Aug 2020 01:38:48

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:38:43', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1fe483d0-2b84-42a6-a558-670db8c72be9'	System	15 Aug 2020 01:38:48
User entered 'No (N)'	System	15 Aug 2020 01:38:48

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:38:46', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1fe483d0-2b84-42a6-a558-670db8c72be9'	System	15 Aug 2020 01:38:48
User entered '14 Aug 2020 20:38'	System	15 Aug 2020 01:38:48

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '14 Aug 2020 17:25'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 2'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:40:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:23:08', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '36260be7-461c-43d9-b10d-bad5da012878'	System	15 Aug 2020 17:23:19
User entered 'Yes (Y)'	System	15 Aug 2020 17:23:19

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:40:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:23:11', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '36260be7-461c-43d9-b10d-bad5da012878' User entered '97.7'	System	15 Aug 2020 17:23:19
	System	15 Aug 2020 17:23:19

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:23:14', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '36260be7-461c-43d9-b10d-bad5da012878'	System	15 Aug 2020 17:23:19
User entered 'No (N)'	System	15 Aug 2020 17:23:19

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:23:17', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '36260be7-461c-43d9-b10d-bad5da012878'	System	15 Aug 2020 17:23:19
User entered '15 Aug 2020 12:23'	System	15 Aug 2020 17:23:19

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 3'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:40:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:59:20', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '31218644-aec1-4c43-a38d-f78513bf95eb'	System	16 Aug 2020 18:00:31
User entered 'Yes (Y)'	System	16 Aug 2020 18:00:31

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:40:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T13:00:23', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '31218644-aec1-4c43-a38d-f78513bf95eb'	System	16 Aug 2020 18:00:31
User entered '98.0'	System	16 Aug 2020 18:00:31

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T13:00:26', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '31218644-aec1-4c43-a38d-f78513bf95eb'	System	16 Aug 2020 18:00:31
User entered 'No (N)'	System	16 Aug 2020 18:00:31

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T13:00:28', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '31218644-aec1-4c43-a38d-f78513bf95eb'	System	16 Aug 2020 18:00:31
User entered '16 Aug 2020 13:00'	System	16 Aug 2020 18:00:31

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 4'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:40:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:13:26', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'be4f83b5-a5d1-4af7-9e5f-b215f399a584'	System	17 Aug 2020 17:13:39
User entered 'Yes (Y)'	System	17 Aug 2020 17:13:39

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:40:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:13:30', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'be4f83b5-a5d1-4af7-9e5f-b215f399a584'	System	17 Aug 2020 17:13:39
User entered '98.2'	System	17 Aug 2020 17:13:39

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:13:32', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'be4f83b5-a5d1-4af7-9e5f-b215f399a584'	System	17 Aug 2020 17:13:39
User entered 'No (N)'	System	17 Aug 2020 17:13:39

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:13:35', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'be4f83b5-a5d1-4af7-9e5f-b215f399a584'	System	17 Aug 2020 17:13:39
User entered '17 Aug 2020 12:13'	System	17 Aug 2020 17:13:39

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 5'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:40:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:26:45', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'be227d55-4cbd-4e41-9892-35b649871bff'	System	18 Aug 2020 19:26:55
User entered 'Yes (Y)'	System	18 Aug 2020 19:26:55

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:40:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:26:48', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'be227d55-4cbd-4e41-9892-35b649871bff'	System	18 Aug 2020 19:26:55
User entered '97.9'	System	18 Aug 2020 19:26:55

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:26:51', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'be227d55-4cbd-4e41-9892-35b649871bff'	System	18 Aug 2020 19:26:55
User entered 'No (N)'	System	18 Aug 2020 19:26:55

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:26:52', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'be227d55-4cbd-4e41-9892-35b649871bff'	System	18 Aug 2020 19:26:55
User entered '18 Aug 2020 14:26'	System	18 Aug 2020 19:26:55

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 6'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:40:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:30', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'f156b16c-b41b-423a-a82c-5c4f6c2a2c9f'	System	19 Aug 2020 17:07:24
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:24

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:40:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:07:17', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'f156b16c-b41b-423a-a82c-5c4f6c2a2c9f'	System	19 Aug 2020 17:07:24
User entered '98.8'	System	19 Aug 2020 17:07:24

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:07:19', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'f156b16c-b41b-423a-a82c-5c4f6c2a2c9f'	System	19 Aug 2020 17:07:24
User entered 'No (N)'	System	19 Aug 2020 17:07:24

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:07:21', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'f156b16c-b41b-423a-a82c-5c4f6c2a2c9f'	System	19 Aug 2020 17:07:24
User entered '19 Aug 2020 12:07'	System	19 Aug 2020 17:07:24

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 7'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:40:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:03:14', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bfd1215e-9433-4f91-8db3-a5baad172fad'	System	20 Aug 2020 17:03:25
User entered 'Yes (Y)'	System	20 Aug 2020 17:03:25

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:40:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:03:17', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bfd1215e-9433-4f91-8db3-a5baad172fad'	System	20 Aug 2020 17:03:25
User entered '98.6'	System	20 Aug 2020 17:03:25

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:03:20', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bfd1215e-9433-4f91-8db3-a5baad172fad'	System	20 Aug 2020 17:03:25
User entered 'No (N)'	System	20 Aug 2020 17:03:25

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:03:22', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bfd1215e-9433-4f91-8db3-a5baad172fad'	System	20 Aug 2020 17:03:25
User entered '20 Aug 2020 12:03'	System	20 Aug 2020 17:03:25

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:18:45', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'd3c85056-5358-46b7-9a17-60d7f957250b'	System	14 Aug 2020 19:19:14
User entered 'None (1)'	System	14 Aug 2020 19:19:14

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'd3c85056-5358-46b7-9a17-60d7f957250b'	System	14 Aug 2020 19:19:14
User entered 'No (N)'	System	14 Aug 2020 19:19:14

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:03', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'd3c85056-5358-46b7-9a17-60d7f957250b'	System	14 Aug 2020 19:19:14
User entered 'No (N)'	System	14 Aug 2020 19:19:14

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:07', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'd3c85056-5358-46b7-9a17-60d7f957250b'	System	14 Aug 2020 19:19:14
User entered 'None (1)'	System	14 Aug 2020 19:19:14

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:11', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'd3c85056-5358-46b7-9a17-60d7f957250b'	System	14 Aug 2020 19:19:14
User entered '14 Aug 2020 14:19'	System	14 Aug 2020 19:19:14

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '14 Aug 2020 14:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '14 Aug 2020 16:30'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:38:51', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7da34410-835d-4942-8aab-a982a9c3360e'	System	15 Aug 2020 01:40:27
User entered 'None (1)'	System	15 Aug 2020 01:40:27

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:38:53', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7da34410-835d-4942-8aab-a982a9c3360e'	System	15 Aug 2020 01:40:27
User entered 'No (N)'	System	15 Aug 2020 01:40:27

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:39:06', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7da34410-835d-4942-8aab-a982a9c3360e'	System	15 Aug 2020 01:40:27
User entered 'Yes (Y)'	System	15 Aug 2020 01:40:27

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:39:59', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7da34410-835d-4942-8aab-a982a9c3360e'	System	15 Aug 2020 01:40:27
User entered '40'	System	15 Aug 2020 01:40:27

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:40:21', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7da34410-835d-4942-8aab-a982a9c3360e'	System	15 Aug 2020 01:40:27
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 01:40:27

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:40:24', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7da34410-835d-4942-8aab-a982a9c3360e'	System	15 Aug 2020 01:40:27
User entered '14 Aug 2020 20:40'	System	15 Aug 2020 01:40:27

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '14 Aug 2020 17:25'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 2'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:23:25', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c2d86f53-ec4d-4d15-9b53-61ce78923292'	System	15 Aug 2020 17:24:41
User entered 'None (1)'	System	15 Aug 2020 17:24:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:23:34', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c2d86f53-ec4d-4d15-9b53-61ce78923292'	System	15 Aug 2020 17:24:41
User entered 'No (N)'	System	15 Aug 2020 17:24:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:24:18', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c2d86f53-ec4d-4d15-9b53-61ce78923292'	System	15 Aug 2020 17:24:41
User entered 'Yes (Y)'	System	15 Aug 2020 17:24:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:24:22', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c2d86f53-ec4d-4d15-9b53-61ce78923292'	System	15 Aug 2020 17:24:41
User entered '30'	System	15 Aug 2020 17:24:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:24:35', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c2d86f53-ec4d-4d15-9b53-61ce78923292'	System	15 Aug 2020 17:24:41
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 17:24:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:24:38', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c2d86f53-ec4d-4d15-9b53-61ce78923292'	System	15 Aug 2020 17:24:41
User entered '15 Aug 2020 12:24'	System	15 Aug 2020 17:24:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 3'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:01:27', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '93a83808-9978-42f2-8efc-ce4031a0c56a'	System	16 Aug 2020 17:02:13
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 17:02:13

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:40:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:01:42', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '93a83808-9978-42f2-8efc-ce4031a0c56a'	System	16 Aug 2020 17:02:13
User entered 'No (N)'	System	16 Aug 2020 17:02:13

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:01:51', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '93a83808-9978-42f2-8efc-ce4031a0c56a'	System	16 Aug 2020 17:02:13
User entered 'No (N)'	System	16 Aug 2020 17:02:13

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:06', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '93a83808-9978-42f2-8efc-ce4031a0c56a'	System	16 Aug 2020 17:02:13
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 17:02:13

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:10', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '93a83808-9978-42f2-8efc-ce4031a0c56a'	System	16 Aug 2020 17:02:13
User entered '16 Aug 2020 12:02'	System	16 Aug 2020 17:02:13

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 4'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:13:43', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '760a7cc4-1688-48b8-a351-de968f07fd48'	System	17 Aug 2020 17:14:05
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 17:14:05

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:40:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:13:45', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '760a7cc4-1688-48b8-a351-de968f07fd48'	System	17 Aug 2020 17:14:05
User entered 'No (N)'	System	17 Aug 2020 17:14:05

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:13:52', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '760a7cc4-1688-48b8-a351-de968f07fd48'	System	17 Aug 2020 17:14:05
User entered 'No (N)'	System	17 Aug 2020 17:14:05

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:13:56', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '760a7cc4-1688-48b8-a351-de968f07fd48'	System	17 Aug 2020 17:14:05
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 17:14:05

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:13:59', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '760a7cc4-1688-48b8-a351-de968f07fd48'	System	17 Aug 2020 17:14:05
User entered '17 Aug 2020 12:13'	System	17 Aug 2020 17:14:05

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 5'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:07', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '3b8de9e4-b827-4138-854e-3c72cd63f1c3'	System	18 Aug 2020 19:27:18
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 19:27:18

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:09', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '3b8de9e4-b827-4138-854e-3c72cd63f1c3'	System	18 Aug 2020 19:27:18
User entered 'No (N)'	System	18 Aug 2020 19:27:18

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:11', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '3b8de9e4-b827-4138-854e-3c72cd63f1c3'	System	18 Aug 2020 19:27:18
User entered 'No (N)'	System	18 Aug 2020 19:27:18

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:14', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '3b8de9e4-b827-4138-854e-3c72cd63f1c3'	System	18 Aug 2020 19:27:18
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 19:27:18

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:16', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '3b8de9e4-b827-4138-854e-3c72cd63f1c3'	System	18 Aug 2020 19:27:18
User entered '18 Aug 2020 14:27'	System	18 Aug 2020 19:27:18

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 6'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:16', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bf867f1e-56ad-4a18-84c6-30661295fad0'	System	19 Aug 2020 17:04:31
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:18', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bf867f1e-56ad-4a18-84c6-30661295fad0'	System	19 Aug 2020 17:04:31
User entered 'No (N)'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:20', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bf867f1e-56ad-4a18-84c6-30661295fad0'	System	19 Aug 2020 17:04:31
User entered 'No (N)'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:24', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bf867f1e-56ad-4a18-84c6-30661295fad0'	System	19 Aug 2020 17:04:31
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:26', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bf867f1e-56ad-4a18-84c6-30661295fad0'	System	19 Aug 2020 17:04:31
User entered '19 Aug 2020 12:04'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 7'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:01:05', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '44ffb1d2-15f0-4dbb-bf01-9c1b2663ad3f'	System	20 Aug 2020 17:01:41
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:01:07', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '44ffb1d2-15f0-4dbb-bf01-9c1b2663ad3f'	System	20 Aug 2020 17:01:41
User entered 'No (N)'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:01:09', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '44ffb1d2-15f0-4dbb-bf01-9c1b2663ad3f'	System	20 Aug 2020 17:01:41
User entered 'No (N)'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:01:13', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '44ffb1d2-15f0-4dbb-bf01-9c1b2663ad3f'	System	20 Aug 2020 17:01:41
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:01:15', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '44ffb1d2-15f0-4dbb-bf01-9c1b2663ad3f'	System	20 Aug 2020 17:01:41
User entered '20 Aug 2020 12:01'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:18', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8a18258f-995b-4b85-8c53-a707418ed28f'	System	14 Aug 2020 19:19:51
User entered 'None (0)'	System	14 Aug 2020 19:19:51

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:31', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8a18258f-995b-4b85-8c53-a707418ed28f'	System	14 Aug 2020 19:19:51
User entered 'None (0)'	System	14 Aug 2020 19:19:51

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:34', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8a18258f-995b-4b85-8c53-a707418ed28f'	System	14 Aug 2020 19:19:51
User entered 'None (0)'	System	14 Aug 2020 19:19:51

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:36', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8a18258f-995b-4b85-8c53-a707418ed28f'	System	14 Aug 2020 19:19:51
User entered 'None (0)'	System	14 Aug 2020 19:19:51

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:39', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8a18258f-995b-4b85-8c53-a707418ed28f'	System	14 Aug 2020 19:19:51
User entered 'None (0)'	System	14 Aug 2020 19:19:51

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:43', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8a18258f-995b-4b85-8c53-a707418ed28f'	System	14 Aug 2020 19:19:51
User entered 'None (0)'	System	14 Aug 2020 19:19:51

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:46', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8a18258f-995b-4b85-8c53-a707418ed28f'	System	14 Aug 2020 19:19:51
User entered 'No (N)'	System	14 Aug 2020 19:19:51

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T14:19:49', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8a18258f-995b-4b85-8c53-a707418ed28f'	System	14 Aug 2020 19:19:51
User entered '14 Aug 2020 14:19'	System	14 Aug 2020 19:19:51

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '14 Aug 2020 14:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '14 Aug 2020 16:30'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:40:46', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4b61d241-9f80-43cb-b0b2-211ee1215067'	System	15 Aug 2020 01:41:09
User entered 'None (0)'	System	15 Aug 2020 01:41:09

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:40:49', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4b61d241-9f80-43cb-b0b2-211ee1215067'	System	15 Aug 2020 01:41:09
User entered 'None (0)'	System	15 Aug 2020 01:41:09

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:40:52', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4b61d241-9f80-43cb-b0b2-211ee1215067'	System	15 Aug 2020 01:41:09
User entered 'None (0)'	System	15 Aug 2020 01:41:09

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:40:54', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4b61d241-9f80-43cb-b0b2-211ee1215067'	System	15 Aug 2020 01:41:09
User entered 'None (0)'	System	15 Aug 2020 01:41:09

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:40:57', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4b61d241-9f80-43cb-b0b2-211ee1215067'	System	15 Aug 2020 01:41:09
User entered 'None (0)'	System	15 Aug 2020 01:41:09

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:40:59', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4b61d241-9f80-43cb-b0b2-211ee1215067'	System	15 Aug 2020 01:41:09
User entered 'None (0)'	System	15 Aug 2020 01:41:09

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:41:04', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4b61d241-9f80-43cb-b0b2-211ee1215067'	System	15 Aug 2020 01:41:09
User entered 'No (N)'	System	15 Aug 2020 01:41:09

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-14T20:41:06', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4b61d241-9f80-43cb-b0b2-211ee1215067'	System	15 Aug 2020 01:41:09
User entered '14 Aug 2020 20:41'	System	15 Aug 2020 01:41:09

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '14 Aug 2020 17:25'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 2'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:24:50', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1089a650-9930-4038-9288-c72dc7a8023d'	System	15 Aug 2020 17:25:18
User entered 'No interference with activity (1)'	System	15 Aug 2020 17:25:18

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:24:54', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1089a650-9930-4038-9288-c72dc7a8023d'	System	15 Aug 2020 17:25:18
User entered 'No interference with activity (1)'	System	15 Aug 2020 17:25:18

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:24:59', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1089a650-9930-4038-9288-c72dc7a8023d'	System	15 Aug 2020 17:25:18
User entered 'No interference with activity (1)'	System	15 Aug 2020 17:25:18

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:25:01', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1089a650-9930-4038-9288-c72dc7a8023d'	System	15 Aug 2020 17:25:18
User entered 'None (0)'	System	15 Aug 2020 17:25:18

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:25:06', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1089a650-9930-4038-9288-c72dc7a8023d'	System	15 Aug 2020 17:25:18
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	15 Aug 2020 17:25:18

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:25:11', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1089a650-9930-4038-9288-c72dc7a8023d'	System	15 Aug 2020 17:25:18
User entered 'None (0)'	System	15 Aug 2020 17:25:18

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:25:14', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1089a650-9930-4038-9288-c72dc7a8023d'	System	15 Aug 2020 17:25:18
User entered 'No (N)'	System	15 Aug 2020 17:25:18

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-15T12:25:16', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1089a650-9930-4038-9288-c72dc7a8023d'	System	15 Aug 2020 17:25:18
User entered '15 Aug 2020 12:25'	System	15 Aug 2020 17:25:18

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 3'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:14', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1c8f3e6c-b681-4c93-a97e-e3431d611bce'	System	16 Aug 2020 17:02:38
User entered 'None (0)'	System	16 Aug 2020 17:02:38

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:16', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1c8f3e6c-b681-4c93-a97e-e3431d611bce'	System	16 Aug 2020 17:02:38
User entered 'None (0)'	System	16 Aug 2020 17:02:38

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:23', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1c8f3e6c-b681-4c93-a97e-e3431d611bce'	System	16 Aug 2020 17:02:38
User entered 'None (0)'	System	16 Aug 2020 17:02:38

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:25', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1c8f3e6c-b681-4c93-a97e-e3431d611bce'	System	16 Aug 2020 17:02:38
User entered 'None (0)'	System	16 Aug 2020 17:02:38

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:27', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1c8f3e6c-b681-4c93-a97e-e3431d611bce'	System	16 Aug 2020 17:02:38
User entered 'None (0)'	System	16 Aug 2020 17:02:38

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:30', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1c8f3e6c-b681-4c93-a97e-e3431d611bce'	System	16 Aug 2020 17:02:38
User entered 'None (0)'	System	16 Aug 2020 17:02:38

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:32', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1c8f3e6c-b681-4c93-a97e-e3431d611bce'	System	16 Aug 2020 17:02:38
User entered 'No (N)'	System	16 Aug 2020 17:02:38

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-16T12:02:34', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1c8f3e6c-b681-4c93-a97e-e3431d611bce'	System	16 Aug 2020 17:02:38
User entered '16 Aug 2020 12:02'	System	16 Aug 2020 17:02:38

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 4'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:14:09', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'cd5b16d4-6023-481d-8071-5ec7c02555c8'	System	17 Aug 2020 17:14:29
User entered 'None (0)'	System	17 Aug 2020 17:14:29

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:14:12', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'cd5b16d4-6023-481d-8071-5ec7c02555c8'	System	17 Aug 2020 17:14:29
User entered 'No interference with activity (1)'	System	17 Aug 2020 17:14:29

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:14:15', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'cd5b16d4-6023-481d-8071-5ec7c02555c8'	System	17 Aug 2020 17:14:29
User entered 'None (0)'	System	17 Aug 2020 17:14:29

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:14:17', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'cd5b16d4-6023-481d-8071-5ec7c02555c8'	System	17 Aug 2020 17:14:29
User entered 'None (0)'	System	17 Aug 2020 17:14:29

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:14:19', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'cd5b16d4-6023-481d-8071-5ec7c02555c8'	System	17 Aug 2020 17:14:29
User entered 'None (0)'	System	17 Aug 2020 17:14:29

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:14:21', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'cd5b16d4-6023-481d-8071-5ec7c02555c8'	System	17 Aug 2020 17:14:29
User entered 'None (0)'	System	17 Aug 2020 17:14:29

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:14:23', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'cd5b16d4-6023-481d-8071-5ec7c02555c8'	System	17 Aug 2020 17:14:29
User entered 'No (N)'	System	17 Aug 2020 17:14:29

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-17T12:14:25', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'cd5b16d4-6023-481d-8071-5ec7c02555c8'	System	17 Aug 2020 17:14:29
User entered '17 Aug 2020 12:14'	System	17 Aug 2020 17:14:29

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 5'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:19', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '85610d92-f218-4f24-b523-e25ed44c53b6'	System	18 Aug 2020 19:27:36
User entered 'None (0)'	System	18 Aug 2020 19:27:36

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:22', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '85610d92-f218-4f24-b523-e25ed44c53b6'	System	18 Aug 2020 19:27:36
User entered 'No interference with activity (1)'	System	18 Aug 2020 19:27:36

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:24', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '85610d92-f218-4f24-b523-e25ed44c53b6'	System	18 Aug 2020 19:27:36
User entered 'None (0)'	System	18 Aug 2020 19:27:36

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:25', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '85610d92-f218-4f24-b523-e25ed44c53b6'	System	18 Aug 2020 19:27:36
User entered 'None (0)'	System	18 Aug 2020 19:27:36

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:27', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '85610d92-f218-4f24-b523-e25ed44c53b6'	System	18 Aug 2020 19:27:36
User entered 'None (0)'	System	18 Aug 2020 19:27:36

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:29', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '85610d92-f218-4f24-b523-e25ed44c53b6'	System	18 Aug 2020 19:27:36
User entered 'None (0)'	System	18 Aug 2020 19:27:36

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:31', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '85610d92-f218-4f24-b523-e25ed44c53b6'	System	18 Aug 2020 19:27:36
User entered 'No (N)'	System	18 Aug 2020 19:27:36

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-18T14:27:33', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '85610d92-f218-4f24-b523-e25ed44c53b6'	System	18 Aug 2020 19:27:36
User entered '18 Aug 2020 14:27'	System	18 Aug 2020 19:27:36

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 6'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:03:52', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '716fb6a2-decd-468c-b9f7-4cd3756a9047'	System	19 Aug 2020 17:04:11
User entered 'None (0)'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:03:54', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '716fb6a2-decd-468c-b9f7-4cd3756a9047'	System	19 Aug 2020 17:04:11
User entered 'No interference with activity (1)'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:03:58', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '716fb6a2-decd-468c-b9f7-4cd3756a9047'	System	19 Aug 2020 17:04:11
User entered 'No interference with activity (1)'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '716fb6a2-decd-468c-b9f7-4cd3756a9047'	System	19 Aug 2020 17:04:11
User entered 'None (0)'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:02', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '716fb6a2-decd-468c-b9f7-4cd3756a9047'	System	19 Aug 2020 17:04:11
User entered 'None (0)'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:03', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '716fb6a2-decd-468c-b9f7-4cd3756a9047'	System	19 Aug 2020 17:04:11
User entered 'None (0)'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:05', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '716fb6a2-decd-468c-b9f7-4cd3756a9047'	System	19 Aug 2020 17:04:11
User entered 'No (N)'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-19T12:04:06', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '716fb6a2-decd-468c-b9f7-4cd3756a9047'	System	19 Aug 2020 17:04:11
User entered '19 Aug 2020 12:04'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 7'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:00:40', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '39827486-9928-43c0-afc3-3c6453aadb7'	System	20 Aug 2020 17:01:17
User entered 'No interference with activity (1)'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:00:43', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '39827486-9928-43c0-afc3-3c6453aadbe7'	System	20 Aug 2020 17:01:17
User entered 'No interference with activity (1)'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:00:45', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '39827486-9928-43c0-afc3-3c6453aadbe7'	System	20 Aug 2020 17:01:17
User entered 'No interference with activity (1)'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:00:47', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '39827486-9928-43c0-afc3-3c6453aadbe7'	System	20 Aug 2020 17:01:17
User entered 'None (0)'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:00:49', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '39827486-9928-43c0-afc3-3c6453aadbe7'	System	20 Aug 2020 17:01:17
User entered 'None (0)'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:00:51', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '39827486-9928-43c0-afc3-3c6453aadb7'	System	20 Aug 2020 17:01:17
User entered 'None (0)'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:00:53', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '39827486-9928-43c0-afc3-3c6453aadbe7'	System	20 Aug 2020 17:01:17
User entered 'No (N)'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-20T12:00:55', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '39827486-9928-43c0-afc3-3c6453aadbe7'	System	20 Aug 2020 17:01:17
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	19 Aug 2020 17:04:31
User entered 'Day 8'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:10', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'effcc153-c84b-46c5-b790-1c3fec7f20af'	System	21 Aug 2020 17:30:17
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 17:30:17

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:13', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'effcc153-c84b-46c5-b790-1c3fec7f20af'	System	21 Aug 2020 17:30:17
User entered '21 Aug 2020 12:30'	System	21 Aug 2020 17:30:17

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	20 Aug 2020 17:01:41
User entered 'Day 9'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:04:59', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '2f540569-6929-48f6-bdf1-8b58d53f33a5'	System	22 Aug 2020 17:05:06
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 17:05:06

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:05:01', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '2f540569-6929-48f6-bdf1-8b58d53f33a5'	System	22 Aug 2020 17:05:06
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 17:05:06

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	21 Aug 2020 17:30:17
User entered 'Day 10'	System	21 Aug 2020 17:30:17

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-23T12:04:18', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '9994e6f3-14fc-4f09-a5d0-7986a30b8d5a'	System	23 Aug 2020 17:04:22
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 17:04:22

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-23T12:04:20', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '9994e6f3-14fc-4f09-a5d0-7986a30b8d5a'	System	23 Aug 2020 17:04:22
User entered '23 Aug 2020 12:04'	System	23 Aug 2020 17:04:22

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:30:17

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:30:17

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	22 Aug 2020 17:05:06
User entered 'Day 11'	System	22 Aug 2020 17:05:06

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-24T12:33:31', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bd4ae1eb-0f2e-4ce0-9224-e322284e1257'	System	24 Aug 2020 17:33:37
User entered 'None (1)'	System	24 Aug 2020 17:33:37

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-24T12:33:33', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'bd4ae1eb-0f2e-4ce0-9224-e322284e1257'	System	24 Aug 2020 17:33:37
User entered '24 Aug 2020 12:33'	System	24 Aug 2020 17:33:37

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:05:06

US3382035

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:05:06

US3382035

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	20 Aug 2020 17:01:17
User entered 'Day 8'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:17', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '3f6a5107-a384-4f2f-afe5-84eadf3c1db4'	System	21 Aug 2020 17:30:24
User entered 'None (0)'	System	21 Aug 2020 17:30:24

US3382035

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:19', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '3f6a5107-a384-4f2f-afe5-84eadf3c1db4'	System	21 Aug 2020 17:30:24
User entered '21 Aug 2020 12:30'	System	21 Aug 2020 17:30:24

US3382035

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	19 Aug 2020 17:04:11
User entered 'Day 8'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:23', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8c2a2d18-5ed7-4abc-9e42-ea40f701c089'	System	21 Aug 2020 17:30:28
User entered 'No interference with activity (1)'	System	21 Aug 2020 17:30:28

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:26', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8c2a2d18-5ed7-4abc-9e42-ea40f701c089'	System	21 Aug 2020 17:30:28
User entered '21 Aug 2020 12:30'	System	21 Aug 2020 17:30:28

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	20 Aug 2020 17:01:17
User entered 'Day 9'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:05:12', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8e0fd4a7-919d-40f2-bce2-0c10234c4f8a'	System	22 Aug 2020 17:05:18
User entered 'None (0)'	System	22 Aug 2020 17:05:18

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:05:14', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '8e0fd4a7-919d-40f2-bce2-0c10234c4f8a'	System	22 Aug 2020 17:05:18
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 17:05:18

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	19 Aug 2020 17:04:11
User entered 'Day 8'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:40:51

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:30', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'f1d02654-198f-4efb-b4b0-80e1ecc1989b'	System	21 Aug 2020 17:30:36
User entered 'No interference with activity (1)'	System	21 Aug 2020 17:30:36

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:32', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'f1d02654-198f-4efb-b4b0-80e1ecc1989b'	System	21 Aug 2020 17:30:36
User entered '21 Aug 2020 12:30'	System	21 Aug 2020 17:30:36

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	20 Aug 2020 17:01:17
User entered 'Day 9'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:40:51

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:05:24', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'b6e6bf6e-7651-4bca-8556-4451aaf9f432'	System	22 Aug 2020 17:05:31
User entered 'No interference with activity (1)'	System	22 Aug 2020 17:05:31

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:05:26', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'b6e6bf6e-7651-4bca-8556-4451aaf9f432'	System	22 Aug 2020 17:05:31
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 17:05:31

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	21 Aug 2020 17:30:36
User entered 'Day 10'	System	21 Aug 2020 17:30:36

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:40:51

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-23T12:04:23', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1762669f-fa45-4870-a5cb-f434ba69353e'	System	23 Aug 2020 17:04:30
User entered 'No interference with activity (1)'	System	23 Aug 2020 17:04:30

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-23T12:04:25', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1762669f-fa45-4870-a5cb-f434ba69353e'	System	23 Aug 2020 17:04:30
User entered '23 Aug 2020 12:04'	System	23 Aug 2020 17:04:30

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:30:36

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:30:36

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	22 Aug 2020 17:05:31
User entered 'Day 11'	System	22 Aug 2020 17:05:31

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:40:51

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-24T12:33:40', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1a98d5a1-4f10-484a-93f4-944b1901c640'	System	24 Aug 2020 17:33:46
User entered 'None (0)'	System	24 Aug 2020 17:33:46

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-24T12:33:42', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1a98d5a1-4f10-484a-93f4-944b1901c640'	System	24 Aug 2020 17:33:46
User entered '24 Aug 2020 12:33'	System	24 Aug 2020 17:33:46

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:05:31

US3382035

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:05:31

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	19 Aug 2020 17:04:11
User entered 'Day 8'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:36', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '14ecb212-9ea0-4256-b422-e5a3622a29be'	System	21 Aug 2020 17:30:42
User entered 'No (N)'	System	21 Aug 2020 17:30:42

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:38', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '14ecb212-9ea0-4256-b422-e5a3622a29be'	System	21 Aug 2020 17:30:42
User entered '21 Aug 2020 12:30'	System	21 Aug 2020 17:30:42

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:04:11

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	20 Aug 2020 17:01:17
User entered 'Day 9'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:05:29', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'df686661-b0cf-42e9-adf4-ce68569257cd'	System	22 Aug 2020 17:05:37
User entered 'No (N)'	System	22 Aug 2020 17:05:37

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:05:31', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'df686661-b0cf-42e9-adf4-ce68569257cd'	System	22 Aug 2020 17:05:37
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 17:05:37

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:01:17

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	21 Aug 2020 17:30:17
User entered 'Day 10'	System	21 Aug 2020 17:30:17

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-23T12:04:29', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'fe31b239-d1e7-4c9d-b7e9-9a4c691c4747'	System	23 Aug 2020 17:04:33
User entered 'No (N)'	System	23 Aug 2020 17:04:33

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-23T12:04:30', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'fe31b239-d1e7-4c9d-b7e9-9a4c691c4747'	System	23 Aug 2020 17:04:33
User entered '23 Aug 2020 12:04'	System	23 Aug 2020 17:04:33

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:30:17

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:30:17

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
Data entry locked.	System	22 Aug 2020 17:05:06
User entered 'Day 11'	System	22 Aug 2020 17:05:06

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:40:51

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 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-24T12:33:47', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ef7e526e-44aa-4f82-b59e-17c5285220d0'	System	24 Aug 2020 17:33:54
User entered 'Yes (Y)'	System	24 Aug 2020 17:33:54

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-24T12:33:49', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ef7e526e-44aa-4f82-b59e-17c5285220d0'	System	24 Aug 2020 17:33:54
User entered '24 Aug 2020 12:33'	System	24 Aug 2020 17:33:54

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:05:06

US3382035

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:59
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:05:06

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	19 Aug 2020 17:04:31
User entered 'Day 8'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:40:51

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 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:47', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '51c80bc0-bf15-4038-ac69-11cab0ddaaa6'	System	21 Aug 2020 17:30:54
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 17:30:54

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-21T12:30:49', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '51c80bc0-bf15-4038-ac69-11cab0ddaaa6'	System	21 Aug 2020 17:30:54
User entered '21 Aug 2020 12:30'	System	21 Aug 2020 17:30:54

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:04:31

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	20 Aug 2020 17:01:41
User entered 'Day 9'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:40:51

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 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:05:42', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'e4068e78-3e63-464f-8681-deca1640a1ea'	System	22 Aug 2020 17:05:46
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 17:05:46

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-22T12:05:43', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'e4068e78-3e63-464f-8681-deca1640a1ea'	System	22 Aug 2020 17:05:46
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 17:05:46

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:01:41

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	21 Aug 2020 17:30:54
User entered 'Day 10'	System	21 Aug 2020 17:30:54

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:40:51

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 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-23T12:04:43', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7ef8d9c6-aab5-495c-b7cc-aa0af174631c'	System	23 Aug 2020 17:04:47
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 17:04:47

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-23T12:04:44', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7ef8d9c6-aab5-495c-b7cc-aa0af174631c'	System	23 Aug 2020 17:04:47
User entered '23 Aug 2020 12:04'	System	23 Aug 2020 17:04:47

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:30:54

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:30:54

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	22 Aug 2020 17:05:46
User entered 'Day 11'	System	22 Aug 2020 17:05:46

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:40:51

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 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-24T12:33:54', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'e6d063ce-4208-4954-a0bd-29e2f2a2ace4'	System	24 Aug 2020 17:34:10
User entered 'None (1)'	System	24 Aug 2020 17:34:10

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-08-24T12:33:56', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'e6d063ce-4208-4954-a0bd-29e2f2a2ace4'	System	24 Aug 2020 17:34:10
User entered '24 Aug 2020 12:33'	System	24 Aug 2020 17:34:10

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:05:46

US3382035

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:40:51

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:05:46

US3382035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 22:32:52

US3382035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '22 Aug 2020'	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 22:32:52

US3382035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Contact Made (CONTACT MADE)'	Robin Dotson (b) (4)	11 Sep 2020 22:32:52

US3382035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 22:32:52

US3382035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 22:33:23

US3382035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered 'I'	System	11 Sep 2020 22:33:23

US3382035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 22:43:40

US3382035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
Signature has been broken.	Jayasree Krishnankutty (b) (4)	23 Mar 2021 11:32:34
User entered '29 Aug 2020' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	23 Mar 2021 11:32:34
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '28 Aug 2020'	Robin Dotson (b) (4)	11 Sep 2020 22:43:40

US3382035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
Signature has been broken.	Jayasree Krishnankutty (b) (4)	23 Mar 2021 11:32:34
User entered 'Contact Made (CONTACT MADE)'	Jayasree Krishnankutty (b) (4)	23 Mar 2021 11:32:34
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Contact Not Made (CONTACT NOT MADE)'	Robin Dotson (b) (4)	11 Sep 2020 22:43:40

US3382035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
Signature has been broken.	Jayasree Krishnankutty (b) (4)	23 Mar 2021 11:32:34
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	23 Mar 2021 11:32:34
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'subject missed call'	Robin Dotson (b) (4)	11 Sep 2020 22:43:40

US3382035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 23:04:11

US3382035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:31:05
User entered '1'	System	11 Sep 2020 23:04:11

US3382035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 23:08:19

US3382035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 11:31:07
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'We were unable to contact subject 05-sep and 07-sep. Finally made contact 08-sep' (Site from System).	Devin Teal (b) (4) (b) (4)	30 Sep 2020 22:03:51
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 23:08:19
User entered '08 Sep 2020'	Robin Dotson (b) (4) (b) (4)	11 Sep 2020 23:08:19

US3382035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 23:08:19

US3382035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 23:08:19

US3382035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	11 Sep 2020 23:08:28

US3382035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'I'	System	11 Sep 2020 23:08:28

US3382035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:32:12

US3382035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '11 Sep 2020'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:32:12

US3382035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Clinic (Clinic)'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:32:12

US3382035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'VISIT2'	System	18 Sep 2020 20:32:12

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User accepted default value 'Pre-Dose (PREDOSE)'	Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '11 Sep 2020'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '10:05'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered '11 Sep 2020 10:05'	System	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '98.5' F	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Oral (Oral)'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '62'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'bpm'	System	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '12'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'breaths/min'	System	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '111'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'mmHg'	System	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '76'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'mmHg'	System	18 Sep 2020 20:33:15

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User accepted default value 'Post-Dose (POSTDOSE)'	Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	18 Sep 2020 20:35:25

US3382035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Sikhongi Phungwayo (b) (4)	24 Sep 2020 21:28:42

US3382035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '11 Sep 2020'	(b) (4) Sikhongi Phungwayo (b) (4)	24 Sep 2020 21:28:42

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Michelle Jackson (b) (4)	26 Sep 2020 23:27:56

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) Michelle Jackson (b) (4) (b) (4)	26 Sep 2020 23:27:56

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

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)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Michelle Jackson (b) (4)	26 Sep 2020 23:27:56
	(b) (4)	

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	26 Sep 2020 23:27:56

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Michelle Jackson (b) (4)	26 Sep 2020 23:27:56

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Michelle Jackson (b) (4)	26 Sep 2020 23:27:56

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	26 Sep 2020 23:27:56

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4)	Michelle Jackson (b) (4)
	(b) (4)	26 Sep 2020 23:27:56

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	26 Sep 2020 23:27:56

US3382035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	26 Sep 2020 23:27:56

US3382035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Michelle Jackson (b) (4)	26 Sep 2020 23:30:11
User entered 'No (N)'	(b) (4)	
	Michelle Jackson (b) (4)	26 Sep 2020 23:28:02
	(b) (4)	

US3382035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4)	26 Sep 2020 23:30:11
User entered empty.	Michelle Jackson (b) (4)	26 Sep 2020 23:28:02
	(b) (4)	

US3382035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '10:40' reason for change: Data Entry Error	(b) (4)	
	Robin Dotson (b) (4)	30 Sep 2020 15:07:58
User entered '00:00' reason for change: Data Entry Error	(b) (4)	
	Michelle Jackson (b) (4)	26 Sep 2020 23:30:11
User entered empty.	(b) (4)	
	Michelle Jackson (b) (4)	26 Sep 2020 23:28:02
	(b) (4)	

US3382035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered '11 Sep 2020 10:40'	System	30 Sep 2020 15:07:58
User entered '11 Sep 2020 00:00'	System	26 Sep 2020 23:30:11
User entered empty.	System	26 Sep 2020 23:28:02

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:40:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '11 Sep 2020'	(b) (4) Sikhongi Phungwayo (b) (4)	24 Sep 2020 21:29:44

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sikhongi Phungwayo (b) (4)	24 Sep 2020 21:29:44

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Sikhongi Phungwayo (b) (4)	24 Sep 2020 21:29:44

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '10:30'	(b) (4) Sikhongi Phungwayo (b) (4)	24 Sep 2020 21:29:44

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:51

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered '11 Sep 2020 10:30'	System	24 Sep 2020 21:29:44

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sikhongi Phungwayo (b) (4)	24 Sep 2020 21:29:44

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Sikhongi Phungwayo (b) (4)	24 Sep 2020 21:29:44

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Sikhongi Phungwayo (b) (4)	24 Sep 2020 21:29:44

US3382035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:51

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered empty.	System	24 Sep 2020 21:29:44

US3382035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Michelle Jackson (b) (4)	26 Sep 2020 23:31:52
User entered 'No (N)'	(b) (4)	
	Michelle Jackson (b) (4)	26 Sep 2020 23:30:36
	(b) (4)	

US3382035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered '1'	System	26 Sep 2020 23:31:52
User entered empty.	System	26 Sep 2020 23:30:36

US3382035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 14:10:05

US3382035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '18 Sep 2020'	(b) (4) Michelle Jackson (b) (4)	28 Sep 2020 14:10:05

US3382035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michelle Jackson (b) (4)	28 Sep 2020 14:10:05

US3382035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Michelle Jackson (b) (4)	28 Sep 2020 14:10:05

US3382035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 14:10:41

US3382035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'I'	System	28 Sep 2020 14:10:41

US3382035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 14:10:59

US3382035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '25 Sep 2020'	(b) (4) Michelle Jackson (b) (4)	28 Sep 2020 14:10:59

US3382035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michelle Jackson (b) (4)	28 Sep 2020 14:10:59

US3382035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Michelle Jackson (b) (4)	28 Sep 2020 14:10:59

US3382035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Michelle Jackson (b) (4)	28 Sep 2020 14:11:21

US3382035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'I'	System	28 Sep 2020 14:11:21

US3382035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 18:56:11

US3382035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '06 Oct 2020'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 18:56:11

US3382035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 18:56:11

US3382035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 18:56:11

US3382035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 18:56:14

US3382035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'I'	System	12 Oct 2020 18:56:14

US3382035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 18:57:29

US3382035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-JAN-2021 is reported under Participant Decision Visit/OL-D1 in PPD portal; however, swab sample for 29-JAN-2021 is missing in EDC. Kindly review if the swab sample was collected, if yes, update the data as appropriate, else clarify ' (Site from DM).		25 Mar 2021 10:12:30
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-JAN-2021 is reported under Participant Decision Visit/OL-D1 in PPD portal; however, swab sample for 29-JAN-2021 is missing in EDC. Kindly review if the swab sample was collected, if yes, update the data as appropriate, else clarify ' answered with 'Swab sample was collected for OL-1 visit on 29-JAN-2021; however, the swab time was inadvertently not recorded in the chart. Date of swab collection entered in the Participant Decision Visit/OL-D1 folder.' (Site from DM).	Jayasree Krishnankutty (b) (4)	21 Mar 2021 04:00:47
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-JAN-2021 is reported under Participant Decision Visit/OL-D1 in PPD portal; however, swab sample for 29-JAN-2021 is missing in EDC. Kindly review if the swab sample was collected, if yes, update the data as appropriate, else clarify ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 06:28:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:58:10
User entered '09 Oct 2020'	Robin Dotson (b) (4) (b) (4)	12 Oct 2020 18:57:29

US3382035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Clinic (Clinic)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 18:57:29

US3382035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'VISIT3'	System	12 Oct 2020 18:57:29

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '09 Oct 2020'	Robin Dotson (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '11:24'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered '09 Oct 2020 11:24'	System	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '98.9' F	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Oral (Oral)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '61'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'bpm'	System	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '15'	Robin Dotson (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'breaths/min'	System	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '118'	Robin Dotson (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'mmHg'	System	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '79'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'mmHg'	System	12 Oct 2020 19:17:06

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07

US3382035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07

US3382035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'No (N)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:17:14

US3382035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:17:14

US3382035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:19:26

US3382035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '09 Oct 2020'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:19:26

US3382035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '11:51'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:19:26

US3382035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered '09 Oct 2020 11:51'	System	12 Oct 2020 19:19:26

US3382035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	12 Oct 2020 19:19:35

US3382035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered '1'	System	12 Oct 2020 19:19:35

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 64'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-10-16T13:17:09', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1d990f98-8be6-48a4-ba49-a7e06ad0bec4'	System	16 Oct 2020 18:17:19
User entered 'No (N)'	System	16 Oct 2020 18:17:19

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-10-16T13:17:13', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1d990f98-8be6-48a4-ba49-a7e06ad0bec4'	System	16 Oct 2020 18:17:19
User entered 'No (N)'	System	16 Oct 2020 18:17:19

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-10-16T13:17:16', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1d990f98-8be6-48a4-ba49-a7e06ad0bec4'	System	16 Oct 2020 18:17:19
User entered '16 Oct 2020 13:17:16'	System	16 Oct 2020 18:17:19

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 71'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-10-21T00:05:38', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'b65c2c19-78f3-489a-8a42-96f2d2f02914'	System	21 Oct 2020 05:05:46
User entered 'No (N)'	System	21 Oct 2020 05:05:46

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-10-21T00:05:41', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'b65c2c19-78f3-489a-8a42-96f2d2f02914'	System	21 Oct 2020 05:05:46
User entered 'No (N)'	System	21 Oct 2020 05:05:46

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-10-21T00:05:43', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'b65c2c19-78f3-489a-8a42-96f2d2f02914' User entered '21 Oct 2020 00:05:43'	System	21 Oct 2020 05:05:46
	System	21 Oct 2020 05:05:46

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 78'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-10-28T00:11:06', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '6398a95f-e5ef-4317-a880-1c6ba6dc0799'	System	28 Oct 2020 05:11:14
User entered 'No (N)'	System	28 Oct 2020 05:11:14

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-10-28T00:11:09', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '6398a95f-e5ef-4317-a880-1c6ba6dc0799'	System	28 Oct 2020 05:11:14
User entered 'No (N)'	System	28 Oct 2020 05:11:14

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-10-28T00:11:11', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '6398a95f-e5ef-4317-a880-1c6ba6dc0799'	System	28 Oct 2020 05:11:14
User entered '28 Oct 2020 00:11:11'	System	28 Oct 2020 05:11:14

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 92'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-11-11T00:01:22', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'b257043e-7192-4820-93aa-ba7a6a174650'	System	11 Nov 2020 06:01:37
User entered 'No (N)'	System	11 Nov 2020 06:01:37

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-11-11T00:01:26', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'b257043e-7192-4820-93aa-ba7a6a174650'	System	11 Nov 2020 06:01:37
User entered 'No (N)'	System	11 Nov 2020 06:01:37

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-11-11T00:01:29', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'b257043e-7192-4820-93aa-ba7a6a174650'	System	11 Nov 2020 06:01:37
User entered '11 Nov 2020 00:01:29'	System	11 Nov 2020 06:01:37

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:04
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53
Data entry locked.	System	14 Aug 2020 18:44:58
User entered 'Day 99'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 18:44:58

US3382035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:37:53
Data entry locked.	System	14 Aug 2020 18:44:58
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 18:44:58

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (859e63d013b63826)', Time: '2020-11-24T16:03:23', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4edceaa2-4438-4e4c-aea5-dd00b5ec6fe4'	System	24 Nov 2020 22:03:38
User entered 'No (N)'	System	24 Nov 2020 22:03:38

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (859e63d013b63826)', Time: '2020-11-24T16:03:27', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4edceaa2-4438-4e4c-aea5-dd00b5ec6fe4'	System	24 Nov 2020 22:03:38
User entered 'No (N)'	System	24 Nov 2020 22:03:38

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (859e63d013b63826)', Time: '2020-11-24T16:03:29', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '4edceaa2-4438-4e4c-aea5-dd00b5ec6fe4'	System	24 Nov 2020 22:03:38
User entered '24 Nov 2020 16:03:29'	System	24 Nov 2020 22:03:38

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2020-12-03T22:39:31', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '09b652b8-31cd-45e9-889e-358bbf995213'	System	04 Dec 2020 04:39:37
User entered 'No (N)'	System	04 Dec 2020 04:39:37

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2020-12-03T22:39:34', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '09b652b8-31cd-45e9-889e-358bbf995213'	System	04 Dec 2020 04:39:37
User entered 'No (N)'	System	04 Dec 2020 04:39:37

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2020-12-03T22:39:36', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '09b652b8-31cd-45e9-889e-358bbf995213'	System	04 Dec 2020 04:39:37
User entered '03 Dec 2020 22:39:36'	System	04 Dec 2020 04:39:37

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2020-12-06T02:34:30', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ab2cc5e6-c9e3-4507-a606-c53b1c93c717'	System	06 Dec 2020 08:34:38
User entered 'No (N)'	System	06 Dec 2020 08:34:38

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2020-12-06T02:34:33', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ab2cc5e6-c9e3-4507-a606-c53b1c93c717'	System	06 Dec 2020 08:34:38
User entered 'No (N)'	System	06 Dec 2020 08:34:38

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2020-12-06T02:34:36', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ab2cc5e6-c9e3-4507-a606-c53b1c93c717'	System	06 Dec 2020 08:34:38
User entered '06 Dec 2020 02:34:36'	System	06 Dec 2020 08:34:38

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2020-12-13T00:04:49', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '2be32092-6780-4711-944f-47b9c17a5db5'	System	13 Dec 2020 06:05:00
User entered 'No (N)'	System	13 Dec 2020 06:05:00

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2020-12-13T00:04:52', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '2be32092-6780-4711-944f-47b9c17a5db5'	System	13 Dec 2020 06:05:00
User entered 'No (N)'	System	13 Dec 2020 06:05:00

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2020-12-13T00:04:54', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '2be32092-6780-4711-944f-47b9c17a5db5'	System	13 Dec 2020 06:05:00
User entered '13 Dec 2020 00:04:54'	System	13 Dec 2020 06:05:00

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2020-12-20T00:02:41', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'a50c9365-63cf-4394-9527-e90af334a7a1'	System	20 Dec 2020 06:02:58
User entered 'No (N)'	System	20 Dec 2020 06:02:58

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2020-12-20T00:02:44', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'a50c9365-63cf-4394-9527-e90af334a7a1'	System	20 Dec 2020 06:02:58
User entered 'No (N)'	System	20 Dec 2020 06:02:58

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2020-12-20T00:02:46', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'a50c9365-63cf-4394-9527-e90af334a7a1' User entered '20 Dec 2020 00:02:46'	System	20 Dec 2020 06:02:58
	System	20 Dec 2020 06:02:58

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2020-12-31T14:28:24', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'f4ad1ea6-2ac0-4fbf-a144-2d5f13887bec'	System	31 Dec 2020 20:28:36
User entered 'No (N)'	System	31 Dec 2020 20:28:36

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2020-12-31T14:28:28', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'f4ad1ea6-2ac0-4fbf-a144-2d5f13887bec'	System	31 Dec 2020 20:28:36
User entered 'No (N)'	System	31 Dec 2020 20:28:36

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2020-12-31T14:28:30', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'f4ad1ea6-2ac0-4fbf-a144-2d5f13887bec'	System	31 Dec 2020 20:28:36
User entered '31 Dec 2020 14:28:30'	System	31 Dec 2020 20:28:36

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-01-06T16:52:05', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '591cae44-2dc3-41c8-b5d7-66c36e0dbf93'	System	06 Jan 2021 22:52:15
User entered 'No (N)'	System	06 Jan 2021 22:52:15

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-01-06T16:52:08', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '591cae44-2dc3-41c8-b5d7-66c36e0dbf93'	System	06 Jan 2021 22:52:15
User entered 'No (N)'	System	06 Jan 2021 22:52:15

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-01-06T16:52:10', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '591cae44-2dc3-41c8-b5d7-66c36e0dbf93'	System	06 Jan 2021 22:52:15
User entered '06 Jan 2021 16:52:10'	System	06 Jan 2021 22:52:15

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-01-13T12:02:58', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '564f9a9b-71a5-4aed-8116-c4d9c5b358d1'	System	13 Jan 2021 18:03:10
User entered 'No (N)'	System	13 Jan 2021 18:03:10

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-01-13T12:03:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '564f9a9b-71a5-4aed-8116-c4d9c5b358d1'	System	13 Jan 2021 18:03:10
User entered 'No (N)'	System	13 Jan 2021 18:03:10

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-01-13T12:03:02', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '564f9a9b-71a5-4aed-8116-c4d9c5b358d1'	System	13 Jan 2021 18:03:10
User entered '13 Jan 2021 12:03:02'	System	13 Jan 2021 18:03:10

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-01-17T11:21:39', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7b665807-e6d2-43d4-9bbe-485dd9143eaa'	System	17 Jan 2021 17:21:54
User entered 'No (N)'	System	17 Jan 2021 17:21:54

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-01-17T11:21:50', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7b665807-e6d2-43d4-9bbe-485dd9143eaa'	System	17 Jan 2021 17:21:54
User entered 'No (N)'	System	17 Jan 2021 17:21:54

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-01-17T11:21:53', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '7b665807-e6d2-43d4-9bbe-485dd9143eaa'	System	17 Jan 2021 17:21:54
User entered '17 Jan 2021 11:21:53'	System	17 Jan 2021 17:21:54

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-01-28T12:20:12', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c8a80d82-3319-4f66-811e-7962092dcb37'	System	28 Jan 2021 18:20:20
User entered 'No (N)'	System	28 Jan 2021 18:20:20

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-01-28T12:20:14', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c8a80d82-3319-4f66-811e-7962092dcb37'	System	28 Jan 2021 18:20:20
User entered 'No (N)'	System	28 Jan 2021 18:20:20

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-01-28T12:20:17', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c8a80d82-3319-4f66-811e-7962092dcb37'	System	28 Jan 2021 18:20:20
User entered '28 Jan 2021 12:20:17'	System	28 Jan 2021 18:20:20

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-01-31T00:18:33', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '062a44ab-9000-4755-8da6-ffb780875073'	System	31 Jan 2021 06:18:50
User entered 'Yes (Y)'	System	31 Jan 2021 06:18:50

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-01-31T00:18:35', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '062a44ab-9000-4755-8da6-ffb780875073'	System	31 Jan 2021 06:18:50
User entered 'No (N)'	System	31 Jan 2021 06:18:50

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-01-31T00:18:38', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '062a44ab-9000-4755-8da6-ffb780875073'	System	31 Jan 2021 06:18:50
User entered 'No (N)'	System	31 Jan 2021 06:18:50

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-01-31T00:18:43', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '062a44ab-9000-4755-8da6-ffb780875073'	System	31 Jan 2021 06:18:50
User entered 'No (N)'	System	31 Jan 2021 06:18:50

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-01-31T00:18:49', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '062a44ab-9000-4755-8da6-ffb780875073'	System	31 Jan 2021 06:18:50
User entered '31 Jan 2021 00:18:49'	System	31 Jan 2021 06:18:50

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-02-09T13:24:03', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ea9c084b-8db8-4ccc-b64c-bdfdefbdd349'	System	09 Feb 2021 19:24:17
User entered 'No (N)'	System	09 Feb 2021 19:24:17

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-02-09T13:24:07', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ea9c084b-8db8-4ccc-b64c-bdfdefbdd349'	System	09 Feb 2021 19:24:17
User entered 'No (N)'	System	09 Feb 2021 19:24:17

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-09T13:24:09', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ea9c084b-8db8-4ccc-b64c-bdfdefbdd349'	System	09 Feb 2021 19:24:17
User entered '09 Feb 2021 13:24:09'	System	09 Feb 2021 19:24:17

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-02-14T03:03:13', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c42fa947-afa8-44e3-9241-f079b6e92345'	System	14 Feb 2021 09:03:37
User entered 'Yes (Y)'	System	14 Feb 2021 09:03:37

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-02-14T03:03:16', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c42fa947-afa8-44e3-9241-f079b6e92345'	System	14 Feb 2021 09:03:37
User entered 'No (N)'	System	14 Feb 2021 09:03:37

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-14T03:03:27', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c42fa947-afa8-44e3-9241-f079b6e92345'	System	14 Feb 2021 09:03:37
User entered 'No (N)'	System	14 Feb 2021 09:03:37

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-14T03:03:30', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c42fa947-afa8-44e3-9241-f079b6e92345'	System	14 Feb 2021 09:03:37
User entered 'No (N)'	System	14 Feb 2021 09:03:37

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-14T03:03:35', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c42fa947-afa8-44e3-9241-f079b6e92345'	System	14 Feb 2021 09:03:37
User entered '14 Feb 2021 03:03:35'	System	14 Feb 2021 09:03:37

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-02-25T08:34:57-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ded334c4-f466-4af6-8fb1-090a54eaebe8' User entered 'No (N)'	System	25 Feb 2021 15:53:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-02-25T08:34:59-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ded334c4-f466-4af6-8fb1-090a54eaebe8'	System	25 Feb 2021 15:53:59
User entered 'No (N)'	System	25 Feb 2021 15:53:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-25T08:35:01-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ded334c4-f466-4af6-8fb1-090a54eaebe8'	System	25 Feb 2021 15:53:59
User entered '25 Feb 2021 08:35:01'	System	25 Feb 2021 15:53:59

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 (f6a5999e2d175f1d)', Time: '2021-02-28T00:02:24-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'a2920014-9498-449a-9019-1c7c2662bedb'	System	28 Feb 2021 06:03:14
User entered 'Yes (Y)'	System	28 Feb 2021 06:03:14

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-02-28T00:02:26-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'a2920014-9498-449a-9019-1c7c2662bedb'	System	28 Feb 2021 06:03:14
User entered 'No (N)'	System	28 Feb 2021 06:03:14

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-28T00:02:29-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'a2920014-9498-449a-9019-1c7c2662bedb'	System	28 Feb 2021 06:03:14
User entered 'No (N)'	System	28 Feb 2021 06:03:14

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-28T00:02:31-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'a2920014-9498-449a-9019-1c7c2662bedb' User entered 'No (N)'	System	28 Feb 2021 06:03:14
	System	28 Feb 2021 06:03:14

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-28T00:02:34-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'a2920014-9498-449a-9019-1c7c2662bedb' User entered '28 Feb 2021 00:02:34'	System	28 Feb 2021 06:03:14

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

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 (f6a5999e2d175f1d)', Time: '2021-03-08T15:54:22-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '14333442-207c-4984-b56a-3187e7508d51'	System	08 Mar 2021 21:54:29
User entered 'No (N)'	System	08 Mar 2021 21:54:29

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-03-08T15:54:24-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '14333442-207c-4984-b56a-3187e7508d51'	System	08 Mar 2021 21:54:29
User entered 'No (N)'	System	08 Mar 2021 21:54:29

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-03-08T15:54:26-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '14333442-207c-4984-b56a-3187e7508d51'	System	08 Mar 2021 21:54:29
User entered '08 Mar 2021 15:54:26'	System	08 Mar 2021 21:54:29

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-03-23T11:04:01-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1227f9aa-e4f8-42ad-bd6e-72cec92f576b'	System	23 Mar 2021 16:13:21
User entered 'No (N)'	System	23 Mar 2021 16:13:21

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-03-23T11:04:03-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1227f9aa-e4f8-42ad-bd6e-72cec92f576b'	System	23 Mar 2021 16:13:21
User entered 'No (N)'	System	23 Mar 2021 16:13:21

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-03-23T11:04:06-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '1227f9aa-e4f8-42ad-bd6e-72cec92f576b'	System	23 Mar 2021 16:13:21
User entered '23 Mar 2021 11:04:06'	System	23 Mar 2021 16:13:21

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-03-30T11:27:07-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'd496e630-e419-43e3-be4e-34a4348d4d43'	System	30 Mar 2021 16:27:15
User entered 'No (N)'	System	30 Mar 2021 16:27:15

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-03-30T11:27:09-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'd496e630-e419-43e3-be4e-34a4348d4d43'	System	30 Mar 2021 16:27:15
User entered 'No (N)'	System	30 Mar 2021 16:27:15

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-03-30T11:27:12-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'd496e630-e419-43e3-be4e-34a4348d4d43'	System	30 Mar 2021 16:27:15
User entered '30 Mar 2021 11:27:12'	System	30 Mar 2021 16:27:15

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-04-04T01:12:30-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '6f2354e9-c218-4fc8-aa9d-b049fd6e85be' User entered 'No (N)'	System	04 Apr 2021 06:12:35
	System	04 Apr 2021 06:12:35

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-04-04T01:12:32-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '6f2354e9-c218-4fc8-aa9d-b049fd6e85be'	System	04 Apr 2021 06:12:35
User entered 'No (N)'	System	04 Apr 2021 06:12:35

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-04-04T01:12:34-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '6f2354e9-c218-4fc8-aa9d-b049fd6e85be'	System	04 Apr 2021 06:12:35
User entered '04 Apr 2021 01:12:34'	System	04 Apr 2021 06:12:35

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-04-13T12:19:13-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ce1c7a54-4891-41b7-b60c-6e40c5bcee00' User entered 'No (N)'	System	13 Apr 2021 17:19:23
	System	13 Apr 2021 17:19:23

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-04-13T12:19:15-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ce1c7a54-4891-41b7-b60c-6e40c5bcee00'	System	13 Apr 2021 17:19:23
User entered 'No (N)'	System	13 Apr 2021 17:19:23

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-04-13T12:19:17-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'ce1c7a54-4891-41b7-b60c-6e40c5bcee00'	System	13 Apr 2021 17:19:23
User entered '13 Apr 2021 12:19:17'	System	13 Apr 2021 17:19:23

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-04-20T09:10:58-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '42b7c9c6-018e-4579-a58d-b4a15424fc7b' User entered 'No (N)'	System	20 Apr 2021 14:11:19
	System	20 Apr 2021 14:11:19

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-04-20T09:11:13-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '42b7c9c6-018e-4579-a58d-b4a15424fc7b'	System	20 Apr 2021 14:11:19
User entered 'No (N)'	System	20 Apr 2021 14:11:19

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-04-20T09:11:15-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '42b7c9c6-018e-4579-a58d-b4a15424fc7b' User entered '20 Apr 2021 09:11:15'	System	20 Apr 2021 14:11:19
	System	20 Apr 2021 14:11:19

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-04-27T07:38:31-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '6796947c-af91-429a-8308-ead58c710974' User entered 'No (N)'	System	29 Apr 2021 00:09:35
	System	29 Apr 2021 00:09:35

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-04-27T07:38:33-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '6796947c-af91-429a-8308-ead58c710974'	System	29 Apr 2021 00:09:35
User entered 'No (N)'	System	29 Apr 2021 00:09:35

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-04-27T07:38:35-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '6796947c-af91-429a-8308-ead58c710974'	System	29 Apr 2021 00:09:35
User entered '27 Apr 2021 07:38:35'	System	29 Apr 2021 00:09:35

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[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 (f6a5999e2d175f1d)', Time: '2021-05-03T13:10:43-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '5246314e-8d39-49fe-bc20-427e5f4c7fbb'	System	03 May 2021 18:10:50
User entered 'No (N)'	System	03 May 2021 18:10:50

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

Have you been exposed to someone with 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 (f6a5999e2d175f1d)', Time: '2021-05-03T13:10:46-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '5246314e-8d39-49fe-bc20-427e5f4c7fbb'	System	03 May 2021 18:10:50
User entered 'No (N)'	System	03 May 2021 18:10:50

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-05-03T13:10:48-05:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: '5246314e-8d39-49fe-bc20-427e5f4c7fbb'	System	03 May 2021 18:10:50
User entered '03 May 2021 13:10:48'	System	03 May 2021 18:10:50

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:37:53

US3382035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:37:53
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:37:53

US3382035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:40:51

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-28T00:02:14-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c246af84-75d5-43b7-bab8-8cc182ada4ae'	System	28 Feb 2021 06:02:51
User entered 'No (N)'	System	28 Feb 2021 06:02:51

US3382035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:40:51

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:44:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6a5999e2d175f1d)', Time: '2021-02-28T00:02:17-06:00', User OID: 'PatientReportedOutcome (US3382035)', ODM File OID: 'c246af84-75d5-43b7-bab8-8cc182ada4ae'	System	28 Feb 2021 06:02:51
User entered '28 Feb 2021 00:02:17'	System	28 Feb 2021 06:02:51

US3382035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	30 Nov 2020 19:20:27

US3382035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '06 Nov 2020'	(b) (4) Robin Dotson (b) (4) (b) (4)	30 Nov 2020 19:20:27

US3382035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Robin Dotson (b) (4) (b) (4)	30 Nov 2020 19:20:27

US3382035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4) Robin Dotson (b) (4) (b) (4)	30 Nov 2020 19:20:27

US3382035

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'Yes (Y)'	(b) (4) Robin Dotson (b) (4) (b) (4)	30 Nov 2020 19:20:35

US3382035

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:07:07
User entered 'I'	System	30 Nov 2020 19:20:35

US3382035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:18

US3382035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered '11 Dec 2020'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:18

US3382035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:18

US3382035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:18

US3382035

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:22

US3382035

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered 'I'	System	07 Feb 2021 18:23:22

US3382035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:53

US3382035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered '09 Jan 2021'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:53

US3382035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:53

US3382035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:53

US3382035

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:23:56

US3382035

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered 'I'	System	07 Feb 2021 18:23:56

US3382035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:52:52

US3382035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered '08 Feb 2021'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:52:52

US3382035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:52:52

US3382035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	25 Mar 2021 17:52:52

US3382035

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:52:59

US3382035

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered 'I'	System	25 Mar 2021 17:52:59

US3382035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:53:30

US3382035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered '12 Mar 2021'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:53:30

US3382035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered 'Clinic (Clinic)'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:53:30

US3382035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered 'VISIT4'	System	25 Mar 2021 17:53:30

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered 'No (N)'	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered empty.	System	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered empty.	System	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered empty.	System	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered empty.	System	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	30 Mar 2021 19:58:20
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered empty.	System	30 Mar 2021 17:31:28

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09

US3382035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09

US3382035

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered 'No (N)'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:53:33

US3382035

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	25 Mar 2021 17:53:33

US3382035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:54:42

US3382035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered '12 Mar 2021'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:54:42

US3382035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered '11:38'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:54:42

US3382035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered '12 Mar 2021 11:38'	System	25 Mar 2021 17:54:42

US3382035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	25 Mar 2021 17:54:47

US3382035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:20:09
User entered '1'	System	25 Mar 2021 17:54:47

US3382035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 19:15:55

US3382035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
User entered '9 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 19:15:55

US3382035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Apr 2021 19:15:55

US3382035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 19:15:55

US3382035

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 19:16:05

US3382035

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 19:16:05

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:40:51

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:38
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:53
User closed query 'Per GCL Lab Recon: GCL has Swab sample with date of 24AUG2020. Please reconcile or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:16:25
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
Query 'Per GCL Lab Recon: GCL has Swab sample with date of 24AUG2020. Please reconcile or clarify' answered with 'Subject was contacted on 22 AUG 2020 for D8 safety call and subject reported symptoms of SARS-COV-2 and an illness visit was scheduled for 24 AUG 2020 per subject's convenience. Coincidentally, on 24-AUG-2021, the result of the 14 AUG 2021 (screening visit/day 1) NP swab results comes in as COVID 19 positive. On 24-AUG-2020, at the scheduled illness visit, another NP swab was taken, which resulted negative on 28-AUG-2020.' (Site from DM).	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:28:05
User opened query 'Per GCL Lab Recon: GCL has Swab sample with date of 24AUG2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 15:09:59
User entered '22 Aug 2020' reason for change: Data Entry Error	Michelle Jackson (b) (4)	28 Sep 2020 18:54:07
User entered '24 Aug 2020'	Michelle Jackson (b) (4)	28 Sep 2020 14:23:26

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:40:51

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:38
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:53
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
	(b) (4)	
User entered '15:18' reason for change: Data Entry Error	Michelle Jackson (b) (4)	28 Sep 2020 18:54:07
	(b) (4)	
User entered '11:15'	Michelle Jackson (b) (4)	28 Sep 2020 14:23:26
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:40:51

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:38
User entered '22 Aug 2020 15:18'	System	28 Sep 2020 18:54:07
User entered '24 Aug 2020 11:15'	System	28 Sep 2020 14:23:26

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:40:51

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:38
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:53
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
	(b) (4)	
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Michelle Jackson (b) (4)	28 Sep 2020 18:54:07
	(b) (4)	
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Michelle Jackson (b) (4)	28 Sep 2020 14:23:26
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:40:51

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:38
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:53
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 14:23:26

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'Day 1 (Day 1)'	(b) (4) Sinikka Green (b) (4) (b) (4)	31 Mar 2021 15:16:31

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
Signature has been broken.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06
User entered '24 Aug 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered '16 Aug 2020'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered '0'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered '97'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered '%'	System	31 Mar 2021 15:16:31

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered '97.9' F	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'Mild (Mild)'	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'Mild (Mild)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'Mild (Mild)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'Mild (Mild)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'None (None)'	Sinikka Green (b) (4)	31 Mar 2021 15:16:31
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 2 (Day 2)'	(b) (4) Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:35:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 17:35:45
User entered '25 Aug 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 22:02:06
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered '0'	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered empty.	System	31 Mar 2021 22:02:06

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	31 Mar 2021 22:02:06

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 3 (Day 3)'	(b) (4) Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '26 Aug 2020'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'l'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered empty.	System	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 4 (Day 4)'	(b) (4) Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '27 Aug 2020'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'l'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered empty.	System	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4) Colleen Jacobsen (b) (4)	01 Apr 2021 17:47:12
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 17:39:09
User entered '28 Aug 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered '0'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered empty.	System	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) Colleen Jacobsen (b) (4)	01 Apr 2021 17:47:12
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 17:39:09
User entered '29 Aug 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '0'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered empty.	System	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) Colleen Jacobsen (b) (4)	01 Apr 2021 17:47:12
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 17:39:09
User entered '30 Aug 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '0'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '97' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered '%'	System	01 Apr 2021 17:39:09
User entered empty.	System	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Colleen Jacobsen (b) (4)	01 Apr 2021 17:47:12
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 17:39:09
User entered '31 Aug 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered '0'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered empty.	System	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Colleen Jacobsen (b) (4)	01 Apr 2021 17:47:12
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 17:39:09
User entered '01 Sep 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered '0'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered empty.	System	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) Colleen Jacobsen (b) (4)	01 Apr 2021 17:47:12
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 17:39:09
User entered '02 Sep 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '0'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '94' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered '%'	System	01 Apr 2021 17:39:09
User entered empty.	System	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) Colleen Jacobsen (b) (4)	01 Apr 2021 17:47:12
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 17:39:09
User entered '03 Sep 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 17:35:45
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '0'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '95' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
User entered '%'	System	01 Apr 2021 17:39:09
User entered empty.	System	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered '98.2' F reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Apr 2021 17:39:09
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'Mild (Mild)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:40:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:44
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:13
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
	(b) (4)	
User entered 'None (None)'	Colleen Jacobsen (b) (4)	01 Apr 2021 17:35:45

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:40:51

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:29
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	14 Apr 2021 18:03:21
Signature has been broken.	(b) (4)	
	Sinikka Green (b) (4)	14 Apr 2021 14:44:40
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Sinikka Green (b) (4)	14 Apr 2021 14:44:40
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered '14 Aug 2020'	(b) (4)	
	Michelle Jackson (b) (4)	28 Sep 2020 19:05:26
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:40:51

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:29
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 19:05:26
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:40:51

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:29
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User closed query 'Per CDM re-query: Thank you for your answer. However, AE form is still not added. Please consider adding missing AE. Thank you!' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 09:45:04
Query 'Per CDM re-query: Thank you for your answer. However, AE form is still not added. Please consider adding missing AE. Thank you!' answered with 'updated' (Site from DM).	Sinikka Green (b) (4)	19 Jan 2021 20:56:22
	(b) (4)	
User opened query 'Per CDM re-query: Thank you for your answer. However, AE form is still not added. Please consider adding missing AE. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:53:47
User closed query 'Per CDM: Please be aware that Adverse Event form is not presented. Please consider adding missing Adverse Event form for Covid-19 positive test. Thank you!' (Site from DM).		09 Dec 2020 09:53:47
Query 'Per CDM: Please be aware that Adverse Event form is not presented. Please consider adding missing Adverse Event form for Covid-19 positive test. Thank you!' answered with 'will create' (Site from DM).	Sinikka Green (b) (4)	02 Dec 2020 18:18:27
	(b) (4)	
User opened query 'Per CDM: Please be aware that Adverse Event form is not presented. Please consider adding missing Adverse Event form for Covid-19 positive test. Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:35:21
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		02 Oct 2020 07:34:37
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE form present' (Site from System).	Michelle Jackson (b) (4)	30 Sep 2020 15:06:17
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:40:51

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	28 Sep 2020 19:05:26
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 19:05:26

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Folder: Covid-19 Assessment 22 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:40:51

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:29
User closed query 'Per GCL Lab Recon: Swab: Thank you for the response, however since this COVID diagnostic test is in regards to 24 AUG 2020 Illness visit for swab sample, please update the corresponding data accordingly in this form.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:48:46
User signature succeeded.	Sinikka Green (b) (4)	14 Apr 2021 18:03:21
Query 'Per GCL Lab Recon: Swab: Thank you for the response, however since this COVID diagnostic test is in regards to 24 AUG 2020 Illness visit for swab sample, please update the corresponding data accordingly in this form.Thank you.' answered with 'updated' (Site from DM).	(b) (4) Sinikka Green (b) (4)	14 Apr 2021 14:45:51
Signature has been broken.	Sinikka Green (b) (4)	14 Apr 2021 14:44:40
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4) Sinikka Green (b) (4)	14 Apr 2021 14:44:40
User opened query 'Per GCL Lab Recon: Swab: Thank you for the response, however since this COVID diagnostic test is in regards to 24 AUG 2020 Illness visit for swab sample, please update the corresponding data accordingly in this form.Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:23:35
Query 'Per GCL Lab Reconciliation: Swab: In Preclarus report, samples collected for the subject US3382035 on 24AUG2020 under Illness Visit Day 1 with accession number "1F635950734" and Requisition kit id "1F604828782" however same is missing in EDC. Please reconcile the data, if any subject id mismatch or visit mismatch and update as appropriate. Else clarify, thank you.' canceled (Site from DM).		13 Apr 2021 11:16:56

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[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: In Preclarus report, samples collected for the subject US3382035 on 24AUG2020 under Illness Visit Day 1 with accession number " 1F635950734" and Requisition kit id "1F604828782" however same is missing in EDC. Please reconcile the data, if any subject id mismatch or visit mismatch and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 05:42:56
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 24-Aug-2020 for Illness Visit. Please confirm the correct visit date and reconcile. Else clarify. Thank you.		31 Mar 2021 13:10:11
' (Site from DM). User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).		19 Mar 2021 11:51:38
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'A COVID-19 Illness visit for the 24 AUG 2020 was added and those forms completed. ' (Site from DM).	Jayasree Krishnankutty (b) (4)	19 Mar 2021 05:06:19

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[Date of Test](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 24-Aug-2020 for Illness Visit. Please confirm the correct visit date and reconcile. Else clarify. Thank you. ' answered with 'Subject tested positive for COVID-19 with NP swab done at the screening/D1 visit done on 14- AUG-2020 before administration of first dose of the vaccination. This swab returned positive for SARS CoV2 on 24 AUG 2020. Subject was contacted and he reported transient symptoms since the day of vaccination, which he thought was because of his perennial allergies. He was brought in for illness visit on 24-AUG-2020 and another NP swab was taken that day, which resulted as negative.' (Site from DM).	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:57:08
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:10:32
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 24-Aug-2020 for Illness Visit. Please confirm the correct visit date and reconcile. Else clarify. Thank you.		19 Feb 2021 10:18:03
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 24-Aug-202 for Illness Visit. Please confirm the correct visit date and reconcile. Else clarify. Thank you.' canceled (Sit from DM).		19 Feb 2021 10:17:46
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 24-Aug-202 for Illness Visit. Please confirm the correct visit date and reconcile. Else clarify. Thank you.' (Site from DM).		19 Feb 2021 10:17:39

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EAB) (1725)

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[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '14 Aug 2020'	Michelle Jackson (b) (4)	28 Sep 2020 19:05:26
	(b) (4)	

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Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:29
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Michelle Jackson (b) (4)	28 Sep 2020 19:05:26

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:29
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:05:26
	(b) (4)	

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:29
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Michelle Jackson (b) (4)	28 Sep 2020 19:05:26
	(b) (4)	

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:29
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:05:26
	(b) (4)	

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:29
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:05:26

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:52
User entered 'I'	System	28 Sep 2020 19:05:26

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Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'No (N)'	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'No (N)'	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'No (N)'	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'No (N)'	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'No (N)'	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4) Sinikka Green (b) (4)	31 Mar 2021 19:57:23
User entered 'No (N)'	(b) (4) Sinikka Green (b) (4) (b) (4)	31 Mar 2021 15:14:00

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

US3382035

Folder: Covid-19 Assessment 22 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:40:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:10:59
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:45
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:14:00
	(b) (4)	

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Folder: Covid-19 Assessment 22 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:40:51

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:11:04
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:32:49
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'Yes (Y)'	Sinikka Green (b) (4)	31 Mar 2021 15:18:08
	(b) (4)	

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:40:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27,29AUG2020 is recorded under Illness Visit Day 3,5 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)	21 Dec 2020 12:16:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27,29AUG2020 is recorded under Illness Visit Day 3,5 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.' answered with 'Accession number 1F68408' (Site from DM).	Colleen Jacobsen (b) (4)	19 Dec 2020 17:28:23
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27,29AUG2020 is recorded under Illness Visit Day 3,5 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)	04 Dec 2020 06:24:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27,29AUG2020 is recorded under Illness Visit Day 3 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)	04 Dec 2020 06:24:29

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:40:51

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27,29AUG2020 is recorded under Illness Visit Day 3 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). User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6) (b) (4)	04 Dec 2020 06:24:22
	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:40:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
	(b) (4)	
User entered '26 Aug 2020' reason for change: Data Entry Error	Jayasree Krishnankutty	19 Mar 2021 04:53:00
	(b) (4)	
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 26AUG2020 and 28AUG2020 for Day 3 and Day 5 is reported in PPD central lab, however same is reported with 27AUG2020 and 29AUG2020 for Day 3 and Day 7 in EDC. Please reconcile and update if applicable, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:49:15
Query 'Per GCL Lab Recon: Saliva: Sample dated 26AUG2020 and 28AUG2020 for Day 3 and Day 5 is reported in PPD central lab, however same is reported with 27AUG2020 and 29AUG2020 for Day 3 and Day 7 in EDC. Please reconcile and update if applicable, else clarify. Thank you.' answered with 'collection date for Day 3= 27AUG2020; Day 5= 29AUG2020; DAY 7 =31AUG2020' (Site from DM).	Colleen Jacobsen (b) (4)	19 Dec 2020 17:33:45
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 26AUG2020 and 28AUG2020 for Day 3 and Day 5 is reported in PPD central lab, however same is reported with 27AUG2020 and 29AUG2020 for Day 3 and Day 7 in EDC. Please reconcile and update if applicable, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:10:16
Query 'Per GCL Lab Recon: Saliva: Sample dated 26AUG2020, 28AUG2020 and 30AUG2020 for Day 3, Day 5 and Day 7 is recorded under PPD central lab, however day 3, Day 5 is reported under Illness visit with date 27AUG2020 and 29AUG2020 and NA (COVID-19 Negative) for Day 7 in EDC. Please reconcile and update if applicable. Else clarify, thank you.' canceled (Site from DM).		30 Oct 2020 05:06:48

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 26AUG2020, 28AUG2020 and 30AUG2020 for Day 3, Day 5 and Day 7 is recorded under PPD central lab, however day 3, Day 5 is reported under Illness visit with date 27AUG2020 and 29AUG2020 and NA (COVID-19 Negative) for Day 7 in EDC. Please reconcile and update if applicable. Else clarify, thank you.' (Site from DM). User entered '27 Aug 2020'	(b) (4), (b) (6)	30 Oct 2020 05:06:12
	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23
	(b) (4)	

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:40:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
User accepted default value 'Day 5 (Day 5)'	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 19:36:23

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:40:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:11:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:11:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Devin Teal (b) (4)	30 Sep 2020 22:11:39
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 19:36:23
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23
	(b) (4)	

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
	(b) (4)	
User entered '28 Aug 2020' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:53:00
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29AUG2020 is recorded under Illness Visit Day 5 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)	21 Feb 2021 13:19:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29AUG2020 is recorded under Illness Visit Day 5 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).		06 Jan 2021 05:11:51
User entered '29 Aug 2020' reason for change: Data Entry Error	Devin Teal (b) (4)	30 Sep 2020 22:12:03
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23
	(b) (4)	

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:40:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
User accepted default value 'Day 7 (Day 7)'	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 19:36:23

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:40:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:53:00
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:12:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:12:58
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Devin Teal (b) (4)	30 Sep 2020 22:12:58
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 19:36:23
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery1: please confirm if Saliva sample was collected for 31AUG2020, if yes please update the datapoint "Was saliva collected" to yes, if not then please consider to remove the date of collection.Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 04:07:32
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
Query 'Per GCL Lab Reconciliation: Saliva: Requery1: please confirm if Saliva sample was collected for 31AUG2020, if yes please update the datapoint "Was saliva collected" to yes, if not then please consider to remove the date of collection.Thanks' answered with 'The correct D7 saliva collection date was 30 AUG 2020. Date correction done with PPD.' (Site from DM).	(b) (4) Jayasree Krishnankutty (b) (4)	21 Mar 2021 03:50:46
User entered '30 Aug 2020' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:53:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery1: please confirm if Saliva sample was collected for 31AUG2020, if yes please update the datapoint "Was saliva collected" to yes, if not then please consider to remove the date of collection.Thanks' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:22:11
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020, 01SEP2020, 14SEP2020 and 07OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then confirm the correct visit label and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:51:28

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020, 01SEP2020, 14SEP2020 and 07OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then confirm the correct visit label and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'Collection date = 31aug2020' (Site from DM). User entered '31 Aug 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4) [REDACTED] [REDACTED]	19 Dec 2020 17:35:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020, 01SEP2020, 14SEP2020 and 07OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then confirm the correct visit label and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM). User entered empty.	(b) (4), (b) (6) [REDACTED] Michelle Jackson (b) (4) [REDACTED]	10 Nov 2020 05:20:03 28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:40:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020, 01SEP2020, 14SEP2020 and 07OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then confirm the correct visit label and update the details in Saliva collection log under appropriate visit. Else clarify, thank you' (Site from DM).		31 Mar 2021 04:07:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020, 01SEP2020, 14SEP2020 and 07OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then confirm the correct visit label and update the details in Saliva collection log under appropriate visit. Else clarify, thank you' answered with 'Correct saliva sample collection date were D7 30 AUG 2020, D9 01 SEP 2020, D14 06 SEP 2020 and D21 13SEP 2020. PPD was contacted for date correction. Lab personnel error corrected.' (Site from DM).	Jayasree Krishnankutty (b) (4)	21 Mar 2021 03:54:23
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020, 01SEP2020, 14SEP2020 and 07OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then confirm the correct visit label and update the details in Saliva collection log under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:22:42
User accepted default value 'Day 9 (Day 9)'	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:40:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:53:00
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:12:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:12:58
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Devin Teal (b) (4)	30 Sep 2020 22:12:58
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 19:36:23
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered '01 Sep 2020' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:53:00
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:40:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
User accepted default value 'Day 14 (Day 14)'	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:40:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:53:00
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:12:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:12:58
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Devin Teal (b) (4)	30 Sep 2020 22:12:58
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 19:36:23
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
	(b) (4)	
User entered '06 Sep 2020' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:53:00
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23
	(b) (4)	

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:40:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
User accepted default value 'Day 21 (Day 21)'	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:40:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:53:00
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:12:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:12:58
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Devin Teal (b) (4)	30 Sep 2020 22:12:58
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 19:36:23
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
	(b) (4)	
User entered '13 Sep 2020' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 04:53:00
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23
	(b) (4)	

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:40:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
User accepted default value 'Day 28 (Day 28)'	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 19:36:23

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:40:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:12:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:12:58
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Devin Teal (b) (4)	30 Sep 2020 22:12:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 19:36:23
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23
	(b) (4)	

US3382035

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:17
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:41
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:36:23
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:22
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 19:32:27
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:22
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered '24 Aug 2020'	Michelle Jackson (b) (4)	28 Sep 2020 19:32:27
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:22
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered 'Clinic (Clinic)' reason for change:	Michelle Jackson (b) (4)	28 Sep 2020 19:32:38
Data Entry Error	(b) (4)	
User entered 'Home (Home)'	Michelle Jackson (b) (4)	28 Sep 2020 19:32:27
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
User entered 'SICKD1'	System	28 Sep 2020 19:32:27

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered 'No (N)'	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
User entered empty.	System	28 Sep 2020 19:34:37

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered empty.	(b) (4)	
	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
DataPoint set to visible.	(b) (4)	
	System	28 Sep 2020 19:32:27

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	
DataPoint set to visible.	System	28 Sep 2020 19:32:27

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
User entered empty.	System	28 Sep 2020 19:34:37

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
User entered empty.	System	28 Sep 2020 19:34:37

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
User entered empty.	System	28 Sep 2020 19:34:37

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 19:34:37
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
User entered empty.	System	28 Sep 2020 19:34:37

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31

US3382035

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31

US3382035

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
DataPoint Verified.	(b) (4)	
	William Smith (b) (4)	20 Apr 2021 18:20:26
	(b) (4)	
User closed query 'Per source, physical exam was not completed. Please verify and update if necessary.' (Site from CRA).	William Smith (b) (4)	20 Apr 2021 18:20:13
	(b) (4)	
Query 'Per source, physical exam was not completed. Please verify and update if necessary.' answered with 'data corrected' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:15:23
DataPoint Un-verified.		20 Apr 2021 15:15:11
Signature has been broken.		20 Apr 2021 15:15:11
User entered 'No (N)' reason for change: Data Entry Error		20 Apr 2021 15:15:11
User opened query 'Per source, physical exam was not completed. Please verify and update if necessary.' (Site from CRA).	William Smith (b) (4)	19 Apr 2021 20:31:11
	(b) (4)	
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:30:41
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 19:34:54
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
DataPoint Verified.	(b) (4)	
DataPoint Un-verified.	William Smith (b) (4)	20 Apr 2021 18:20:26
Signature has been broken.	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:15:11
DataPoint Verified.	(b) (4)	20 Apr 2021 15:15:11
User signature succeeded.	William Smith (b) (4)	19 Apr 2021 20:30:41
User entered '24 Aug 2020'	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
	Michelle Jackson (b) (4)	28 Sep 2020 19:34:54
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:40:51

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:14
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 19:35:10
	(b) (4)	

US3382035

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:09:31
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:14
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '24 Aug 2020'	Michelle Jackson (b) (4)	28 Sep 2020 19:35:10
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:20
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered 'No (N)'	Colleen Jacobsen (b) (4)	25 Mar 2021 18:02:15

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:20
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	25 Mar 2021 18:02:15

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:20
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	25 Mar 2021 18:02:15

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	25 Mar 2021 18:02:15

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:18:48

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:18:48

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:18:48

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:18:48

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:48
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:18:48

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:27
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:18:53
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:27
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:18:53
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:40:51

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:30
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered 'No (N)'	Sinikka Green (b) (4)	31 Mar 2021 15:19:02
	(b) (4)	

US3382035

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:40:51

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:31:30
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	31 Mar 2021 19:57:23
	(b) (4)	
User entered empty.	Sinikka Green (b) (4)	31 Mar 2021 15:19:02
	(b) (4)	

US3382035

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

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:29:10

US3382035

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

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '29 Jan 2021'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:29:10

US3382035

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

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

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 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Clinic (Clinic)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:29:10

US3382035

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

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'UNBLND_DECIDE'	System	07 Feb 2021 18:29:10

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '29 Jan 2021'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:29:31

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

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 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:03:22

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:29:31

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:03:22

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '29 Jan 2021'	(b) (4)	07 Feb 2021 18:29:31

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Placebo (Placebo)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:29:31

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Placebo (Placebo)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:29:31

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Placebo (Placebo)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:29:31

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:29:31

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '1'	System	07 Feb 2021 18:29:31

US3382035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:40:51

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'I'	System	07 Feb 2021 18:29:31

US3382035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '73.75' in	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '249.4' lb	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '32.30593'	System	07 Feb 2021 18:33:21
DataPoint set to visible.	System	07 Feb 2021 18:29:31

US3382035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '73.75' in	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '249.4' lb	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '32.30593'	System	07 Feb 2021 18:33:21
DataPoint set to visible.	System	07 Feb 2021 18:29:31

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User accepted default value 'Pre-Dose (PREDOSE)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '29 Jan 2021'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '10:34'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '29 Jan 2021 10:34'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '99.0' F	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Oral (Oral)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '79'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'bpm'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '14'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'breaths/min'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '123'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mmHg'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '79'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mmHg'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '73.75' in	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '249.4' lb	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '32.30593'	System	07 Feb 2021 18:33:21
DataPoint set to visible.	System	07 Feb 2021 18:29:31

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User accepted default value 'Post-Dose (POSTDOSE)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '29 Jan 2021'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '11:48'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '29 Jan 2021 11:48'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '98.9' F	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Oral (Oral)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '73'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'bpm'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '14'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'breaths/min'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '118'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mmHg'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '69'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:21

US3382035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mmHg'	System	07 Feb 2021 18:33:21

US3382035

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'No (N)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:26

US3382035

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:26

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:48

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:48

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

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 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:48

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mRNA-1273'	System	07 Feb 2021 18:33:48
DataPoint set to visible.	System	07 Feb 2021 18:29:31

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '29 Jan 2021'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:48

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '11:16'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:48

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '29 Jan 2021 11:16'	System	07 Feb 2021 18:33:48

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Left Arm (LEFT ARM)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:48

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'ONCE'	System	07 Feb 2021 18:33:48

US3382035

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

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'INTRAMUSCULAR'	System	07 Feb 2021 18:33:48

US3382035

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:30:28

US3382035

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '29 Jan 2021'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:30:28

US3382035

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered '10:44' reason for change: Data Entry Error	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:34:27
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Feb 2021 18:33:55
User entered '11:16' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	07 Feb 2021 18:33:55
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Feb 2021 18:30:28
User entered empty.	Colleen Jacobsen (b) (4)	07 Feb 2021 18:30:28

US3382035

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '29 Jan 2021 10:44'	System	07 Feb 2021 18:34:27
User entered '29 Jan 2021 11:16'	System	07 Feb 2021 18:33:55
User entered empty.	System	07 Feb 2021 18:30:28

US3382035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:30:40

US3382035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered '29 Jan 2021'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:30:40

US3382035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 09:50:08
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered with 'time of collection is unknown; inadvertently not recorded. Swab obtained after subject signed updated ICF and after vital signs and lab draw.' (Site from System).	Colleen Jacobsen (b) (4)	19 Mar 2021 19:38:05
Amendment Manager: User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:53:44
User entered empty.	Colleen Jacobsen (b) (4)	07 Feb 2021 18:30:40

US3382035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:40:51

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered empty.	System	07 Feb 2021 18:30:40

US3382035

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

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:30:44

US3382035

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

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '1'	System	07 Feb 2021 18:30:44

US3382035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:14
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26 FEB 2021 is reported under OL-D29/ OL2 visit in PPD Central lab; however, the same Immunogenicity sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		20 Apr 2021 14:26:03
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26 FEB 2021 is reported under OL-D29/ OL2 visit in PPD Central lab; however, the same Immunogenicity sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'THIS SAMPLE WAS COLLECTED IN ERROR. WORKING WITH PPD AND CRA TO DESTROY SAMPLE ' (Site from DM).	Sinikka Green (b) (4) (b) (4)	25 Mar 2021 20:17:56
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26 FEB 2021 is reported under OL-D29/ OL2 visit in PPD Central lab; however, the same Immunogenicity sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:56:09
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:40:29

US3382035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:14
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05 FEB 2021 is reported under OL-D29/ OL2 visit in PPD Central lab; however, the same Immunogenicity sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:55:47
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05 FEB 2021 is reported under OL-D29/ OL2 visit in PPD Central lab; however, the same Immunogenicity sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		23 Mar 2021 09:55:23
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered '05 Feb 2021'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:40:29
	(b) (4)	
	(b) (4)	

US3382035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:14
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:40:29

US3382035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:14
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:40:29

US3382035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:40:33

US3382035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'I'	System	07 Feb 2021 18:40:33

US3382035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '1'	System	07 Feb 2021 18:40:33
DataPoint set to visible.	System	07 Feb 2021 18:40:33

US3382035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 17:58:44

US3382035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit.' (Site from DM).		01 Apr 2021 15:49:14
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit.' answered with 'updated' (Site from DM).	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 16:12:51
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:56:01
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	25 Mar 2021 18:41:07
User entered '26 Feb 2021'	Colleen Jacobsen (b) (4) (b) (4) (b) (4)	25 Mar 2021 17:58:44

US3382035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[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 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Clinic (Clinic)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 17:58:44

US3382035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'OLD29'	System	25 Mar 2021 17:58:44

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User accepted default value 'Pre-Dose (PREDOSE)'	Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '26 Feb 2021'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '11:28'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '26 Feb 2021 11:28'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '97.0' F	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Oral (Oral)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '60'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'bpm'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '14'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'breaths/min'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '118'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mmHg'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '75'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mmHg'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User accepted default value 'Post-Dose (POSTDOSE)'	Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '26 Feb 2021'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '12:20'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '26 Feb 2021 12:20'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '98.5' F	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Oral (Oral)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '74'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'bpm'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '12'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'breaths/min'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '103'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mmHg'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '68'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mmHg'	System	25 Mar 2021 18:00:21

US3382035

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'No (N)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:24

US3382035

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:24

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:51

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:51

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

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 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:51

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'mRNA-1273'	System	25 Mar 2021 18:00:51
DataPoint set to visible.	System	07 Feb 2021 18:40:33

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '26 Feb 2021'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:51

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '11:46'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:51

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered '26 Feb 2021 11:46'	System	25 Mar 2021 18:00:51

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:51

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'ONCE'	System	25 Mar 2021 18:00:51

US3382035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'INTRAMUSCULAR'	System	25 Mar 2021 18:00:51

US3382035

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:00:55

US3382035

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'I'	System	25 Mar 2021 18:00:55

US3382035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:01:20

US3382035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered '05 Mar 2021'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:01:20

US3382035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:01:20

US3382035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:01:20

US3382035

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User signature succeeded.	Sinikka Green (b) (4)	25 Mar 2021 18:41:07
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	25 Mar 2021 18:01:27

US3382035

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:42:07
User entered 'I'	System	25 Mar 2021 18:01:27

US3382035

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:46

US3382035

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:46

US3382035

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:46

US3382035

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 18:31:46

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '11:34'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 11:34'	System	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '59'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '113'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '78'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:33:29

US3382035

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:34:06

US3382035

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:34:06

US3382035

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:34:29

US3382035

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:34:29

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User entered '12:07'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:34:29

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 12:07'	System	01 Apr 2021 18:34:29

US3382035

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:40:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:19:42
User closed query 'Per DM CLR: Medical Attention was checked for DAY 11 on Diary Dose 1. However there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF with "Was this a medically-attended AE?" = YES. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' (Site from DM).		21 Apr 2021 10:25:01
Query 'Per DM CLR: Medical Attention was checked for DAY 11 on Diary Dose 1. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF with "Was this a medically-attended AE?" = YES. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' answered with 'Medical attention was subject being seen at our clinic for an illness visit because his SARS-COV2 swab from Day 1 was positive. The data is captured in the illness visit folder.' (Site from DM).	Jayasree Krishnankutty (b) (4)	20 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:40:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary Dose 1, Fatigue, Injection Site Pain, Muscle aches all over, underarm Gland Swelling or Tenderness lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:39:29
User opened query 'Per DM CLR: Medical Attention was checked for DAY 11 on Diary Dose 1. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF with "Was this a medically-attended AE?" = YES. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention.		20 Apr 2021 01:13:45
' (Site from DM).		
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary Dose 1, Fatigue, Injection Site Pain, Muscle aches all over, underarm Gland Swelling or Tenderness lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.	Jayasree Krishnankutty	19 Apr 2021 18:04:40
' answered with ' Fatigue, Injection Site Pain, Muscle aches all over, underarm Gland Swelling or Tenderness added to AE.' (Site from DM).	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:40:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary Dose 1, Fatigue, Injection Site Pain, Muscle aches all over, underarm Gland Swelling or Tenderness lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 09:09:37
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'Yes (Y)'	(b) (4) Michelle Jackson (b) (4)	28 Sep 2020 14:14:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:16
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:39:44
User entered empty; reason for change Per Query Resolution		20 Jan 2021 12:39:44
Reviewed for Safety.		29 Sep 2020 15:11:46
User entered	System	29 Sep 2020 15:09:39
'USA-US096-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	29 Sep 2020 15:09:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:18
User closed query 'Per MM, Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 11:47:00
Query 'Per MM, Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2. ' answered with 'Study drug was discontinued. The second dose was not given to the subject.' (Site from DM).	Jayasree Krishnankutty (b) (4)	18 Mar 2021 23:33:03
User opened query 'Per MM, Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 11:39:33
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 18:27:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 18:27:16
User closed query 'Per CDM: Please consider changing that to Covid-19 instead of tested positive for covid. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 06:45:58
Data point term sent to Coder	System	20 Jan 2021 14:59:20
Query 'Per CDM: Please consider changing that to Covid-19 instead of tested positive for covid. Thank you!' answered with 'UPDATED' (Site from DM).	Sinikka Green (b) (4) (b) (4)	20 Jan 2021 14:58:30
User entered 'COVID-19 [POSITIVE TEST]' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	20 Jan 2021 14:58:24
User opened query 'Per CDM: Please consider changing that to Covid-19 instead of tested positive for covid. Thank you!' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 09:44:54
Data point term sent to Coder	System	19 Jan 2021 20:58:54
User entered 'tested positive for COVID' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	19 Jan 2021 20:58:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:52:20
Data point term sent to Coder	System	01 Oct 2020 14:50:48
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 PCR test positive - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 15:09:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 15:09:42
	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 14:16:08
User entered 'positive covid pcr test'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:20
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:01
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:52:28
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User entered 'No (N)'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:24
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 11:47:09
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify.' answered with 'AE term is not a solicited reaction. data entry error corrected. Field updated to "No."' (Site from DM).	Jayasree Krishnankutty (b) (4)	18 Mar 2021 23:33:57
Signature has been broken.	Jayasree Krishnankutty (b) (4)	18 Mar 2021 23:22:05
User entered 'No (N)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	18 Mar 2021 23:22:05
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:36:18
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:58:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 08:01:03
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:52:24
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:54
User closed query 'Per CDM: AE term = 'COVID-19 [POSITIVE TEST]' however, 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = No. kindly review and update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 07:25:10
Query 'Per CDM: AE term = 'COVID-19 [POSITIVE TEST]' however, 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = No. kindly review and update as needed. ' answered with 'pt was asymptomatic...' (Site from DM).	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 16:11:19
User opened query 'Per CDM: AE term = 'COVID-19 [POSITIVE TEST]' however, 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = No. kindly review and update as needed. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 22:11:53
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:57:59
User closed query ' PV Query Urgent: Previously event was removed (Oct 2020). Please confirm, Did the subject experience an event of symptomatic positive Covid-19? If yes, please update event term to Covid-19. If no, please change answer to 'No' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 19:35:18
Query ' PV Query Urgent: Previously event was removed (Oct 2020). Please confirm, Did the subject experience an event of symptomatic positive Covid-19? If yes, please update event term to Covid-19. If no, please change answer to 'No' answered with 'PT ASYMPTOMATIC AT THIS DATE' (Site from Safety).	Sinikka Green (b) (4) (b) (4)	20 Jan 2021 15:00:37
User entered 'No (N)' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	20 Jan 2021 15:00:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User opened query ' PV Query Urgent: Previously event was removed (Oct 2020). Please confirm, Did the subject experience an event of symptomatic positive Covid-19? If yes, please update event term to Covid-19. If no, please change answer to 'No' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 12:39:28
Query 'PV Query Urgent: Previously event was removed (Sep 2020). Please confirm, Did the subject experience an event of symptomatic positive Covid-19? If yes, please update event term to Covid-19. If no, please change answer to 'No'. ' canceled (Site from Safety).		20 Jan 2021 12:39:19
User opened query 'PV Query Urgent: Previously event was removed (Sep 2020). Please confirm, Did the subject experience an event of symptomatic positive Covid-19? If yes, please update event term to Covid-19. If no, please change answer to 'No'. ' (Site from Safety).		20 Jan 2021 12:38:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:58:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:04
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:52:17
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User entered 'Yes (Y)'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:52
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '14 Aug 2020' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:58:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:06
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:52:12
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User entered '14 Aug 2020'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:50
User closed query 'Per CDM: Per pg 33 of the CCGs, start time is required for any AE that occurs within 24 hours of dosing. Please confirm and reconcile else clarify. Thank you .' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 07:04:28
Query 'Per CDM: Per pg 33 of the CCGs, start time is required for any AE that occurs within 24 hours of dosing. Please confirm and reconcile else clarify. Thank you .' answered with 'START TIME IS UNKNOWN' (Site from DM).	Colleen Jacobsen (b) (4)	07 Feb 2021 18:35:13
User opened query 'Per CDM: Per pg 33 of the CCGs, start time is required for any AE that occurs within 24 hours of dosing. Please confirm and reconcile else clarify. Thank you .' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 13:41:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 11:00:24
Query 'Data is required. Please provide.' answered with 'unk' (Site from System).	Sinikka Green (b) (4) (b) (4)	19 Jan 2021 20:58:54
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 20:58:33
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 14:16:26
User entered '12:00' reason for change: Data Entry Error	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 14:16:26
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 14:15:41
User entered empty.	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 14:15:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 14:49:55
User entered '14 Aug 2020 12:00'	System	28 Sep 2020 14:16:26
User entered empty.	System	28 Sep 2020 14:15:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:46
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 20:22:03
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'updated' (Site from DM).	Sinikka Green (b) (4)	23 Mar 2021 20:11:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:16:41
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:36:10
User closed query 'Per CDM: Per pg 33 of the CCGs, end time is required for any AE that occurs within 24 hours of dosing. Please confirm and reconcile else clarify. Thank you .' (Site from DM).		08 Feb 2021 07:04:32
Query 'Per CDM: Per pg 33 of the CCGs, end time is required for any AE that occurs within 24 hours of dosing. Please confirm and reconcile else clarify. Thank you .' answered with 'DATE/TIME IS UNKNOWN AT THIS TIME' (Site from DM).	Colleen Jacobsen (b) (4)	07 Feb 2021 18:39:39
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	07 Feb 2021 18:39:05
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	07 Feb 2021 18:38:23
Signature has been broken.	Colleen Jacobsen (b) (4)	07 Feb 2021 18:38:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	07 Feb 2021 18:38:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per pg 33 of the CCGs, end time is required for any AE that occurs within 24 hours of dosing. Please confirm and reconcile else clarify. Thank you .' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	27 Jan 2021 13:42:49
User closed query 'Data is required. Please complete.' (Site from System).	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 08:01:08
User opened query 'Data is required. Please complete.' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:52:01
User entered empty; reason for change Data Entry Error	System	01 Oct 2020 14:49:55
User entered 'Yes (Y)'	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:44
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Mar 2021 20:11:29
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Mar 2021 20:11:29
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Mar 2021 20:10:46
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	23 Mar 2021 20:10:46
User entered '26 Aug 2020' reason for change: Data Entry Error	Sinikka Green (b) (4)	23 Mar 2021 20:10:46
	(b) (4)	
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	19 Mar 2021 03:16:41
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	07 Feb 2021 18:39:17
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	07 Feb 2021 18:39:17
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	07 Feb 2021 18:39:05
Signature has been broken.	Colleen Jacobsen (b) (4)	07 Feb 2021 18:39:05
	(b) (4)	
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	07 Feb 2021 18:39:05
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	

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Generated On: 11 Aug 2021 22:40:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Jan 2021 20:59:08
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Jan 2021 20:59:08
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Jan 2021 20:58:33
User entered '14 Aug 2020' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:58:33
User entered empty.	(b) (4)	
	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Generated On: 11 Aug 2021 22:40:51

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:21:58
Query 'Data is required. Please provide.' answered with 'unk' (Site from System).	Sinikka Green (b) (4) (b) (4)	23 Mar 2021 20:11:46
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Mar 2021 03:16:41
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:57:59
User entered empty.	Michelle Jackson (b) (4) (b) (4)	28 Sep 2020 14:15:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 14:15:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:41
User signature succeeded.	(b) (4) Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4) Sinikka Green (b) (4)	19 Jan 2021 20:58:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:09
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:51:57
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:38
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:58:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:11
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:52:06
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User entered 'No (N)'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:19
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:22
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:24
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:26
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Generated On: 11 Aug 2021 22:40:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:27
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:29
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:31
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:33
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:35
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:36
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:39
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:58:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:13
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:51:47
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:34:32
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).		28 Sep 2020 14:15:41
User entered 'Not Related (NOT RELATED)'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:34:41
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:58:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:14
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:51:42
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User entered 'Not Related (NOT RELATED)'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:35:16
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 11:49:03
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'The reason for withdrawal of the IP drug was because the subject tested positive for SARS COV2 at his screening/day 1 visit.' (Site from System).	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:09:13
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Mar 2021 23:22:05
Signature has been broken.	Jayasree Krishnankutty (b) (4)	18 Mar 2021 23:22:05
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	18 Mar 2021 23:22:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:58:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User closed query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:01:20
		02 Oct 2020 06:23:52
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:51:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or clarify otherwise. Thank you! ' answered with 'data entered in error' (Site from DM).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:51:34
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:51:16
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:51:16
User opened query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or clarify otherwise. Thank you! ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:14:13
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

None

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:35:19
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
Query 'Other action taken is missing. Please check at least one action from the options provided.' canceled (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:21
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Oct 2020 14:49:55
User entered '0' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Sep 2020 14:16:40
User entered '1' reason for change: Data Entry Error	Michelle Jackson (b) (4)	28 Sep 2020 14:16:40
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Sep 2020 14:15:41
User entered '0'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:35:22
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:35:23
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:35:25
User signature succeeded.	(b) (4)	
	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sinikka Green (b) (4)	23 Mar 2021 20:11:29
	(b) (4)	
Signature has been broken.	Colleen Jacobsen (b) (4)	07 Feb 2021 18:39:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	07 Feb 2021 18:39:17
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:59:08
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Sinikka Green (b) (4)	19 Jan 2021 20:58:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:01:18
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Colleen Jacobsen (b) (4)	01 Oct 2020 14:50:46
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:49:55
User entered empty; reason for change Data Entry Error	Colleen Jacobsen (b) (4)	01 Oct 2020 14:49:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:35:28
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:35:30
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Michelle Jackson (b) (4)	28 Sep 2020 14:15:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 14:15:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 14:15:41

US3382035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Productive cough, LLT: Productive cough - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 03:20:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 03:20:59
	(b) (4)	
Data point term sent to Coder	System	19 Mar 2021 03:19:36
User entered 'Productive cough'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '12 Feb 2021'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User entered empty.	System	19 Mar 2021 03:19:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Mar 2021 03:19:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Mar 2021 03:19:28
User entered 'No (N)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:19:28
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Mar 2021 03:19:18
User entered empty.	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:19:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '22 Feb 2021'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User entered empty.	System	19 Mar 2021 03:19:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'None (NONE)'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'I'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 20:23:51
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Mar 2021 03:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User entered '0'	System	19 Mar 2021 03:19:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07
User entered '0'	System	19 Mar 2021 03:19:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:07

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:04:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:04:36
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 17:03:53
User entered 'injection site pain'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Yes (Y)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '16 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User entered empty.	System	19 Apr 2021 17:02:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '23 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User entered empty.	System	19 Apr 2021 17:02:53

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Related (RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Related (RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'None (NONE)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'I'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:02:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User entered '0'	System	19 Apr 2021 17:02:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12
User entered '0'	System	19 Apr 2021 17:02:53

US3382035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:23:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:23:48
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 17:22:14
User entered 'Fatigue'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Yes (Y)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '17 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User entered empty.	System	19 Apr 2021 17:22:12

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '21 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User entered empty.	System	19 Apr 2021 17:22:12

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Related (RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'None (NONE)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:40:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'I'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:22:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User entered '0'	System	19 Apr 2021 17:22:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:40:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17
User entered '0'	System	19 Apr 2021 17:22:12

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:17

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Folder: Adverse Events

Form: Adverse Events (5)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22

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Folder: Adverse Events

Form: Adverse Events (5)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:25:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:25:41
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 17:24:15
User entered 'muscle ache'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Yes (Y)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '19 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User entered empty.	System	19 Apr 2021 17:23:23

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Folder: Adverse Events

Form: Adverse Events (5)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '23 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User entered empty.	System	19 Apr 2021 17:23:23

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Folder: Adverse Events

Form: Adverse Events (5)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Form: Adverse Events (5)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Related (RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'None (NONE)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Generated On: 11 Aug 2021 22:40:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'I'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:23:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User entered '0'	System	19 Apr 2021 17:23:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22
User entered '0'	System	19 Apr 2021 17:23:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:26:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:26:44
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 17:25:16
User entered 'Underarm gland swelling'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Yes (Y)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '16 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User entered empty.	System	19 Apr 2021 17:24:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '23 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User entered empty.	System	19 Apr 2021 17:24:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Related (RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Related (RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'None (NONE)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'I'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:24:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User entered '0'	System	19 Apr 2021 17:24:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28
User entered '0'	System	19 Apr 2021 17:24:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:28

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Folder: Adverse Events

Form: Adverse Events (7)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:29:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:29:03
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 17:28:18
User entered 'Headache'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Yes (Y)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '20 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User entered empty.	System	19 Apr 2021 17:27:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '21 Aug 2020'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User entered empty.	System	19 Apr 2021 17:27:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'No (N)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Related (RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'None (NONE)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'I'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered '0'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User signature succeeded.	Sinikka Green (b) (4)	28 Apr 2021 03:16:24
	(b) (4)	
User entered empty.	Jayasree Krishnankutty	19 Apr 2021 17:27:30
	(b) (4)	

US3382035

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User entered '0'	System	19 Apr 2021 17:27:30

US3382035

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37
User entered '0'	System	19 Apr 2021 17:27:30

US3382035

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:40:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:27:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:40:51

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:19:42
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'Yes (Y)'	(b) (4) Dana Finley (b) (4)	15 Aug 2020 18:59:34

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 14:14:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 14:14:38
Data point term sent to Coder Coding entries removed.	System Michelle Jackson (b) (4)	28 Sep 2020 14:14:03 28 Sep 2020 14:13:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:06:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:06:17
Data point term sent to Coder User entered 'ZOLOFT'	System Dana Finley (b) (4)	15 Aug 2020 19:05:52 15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'anxiety' reason for change: Data Entry Error	Michelle Jackson (b) (4)	28 Sep 2020 14:13:06
	(b) (4)	
User entered 'DEPRESSION'	Dana Finley (b) (4)	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '100'	Dana Finley (b) (4)	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'mg (mg)'	Dana Finley (b) (4)	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'once daily (QD)'	Dana Finley (b) (4)	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:05:43
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:05:43
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:05:43
User entered 'UN UNK 2020'	Dana Finley (b) (4)	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:05:43
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:05:43
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:05:43
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:05:43
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 19:05:43

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:08:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:08:18
Data point term sent to Coder	System	15 Aug 2020 19:06:54
User entered 'EXCEDRIN'	Dana Finley (b) (4)	15 Aug 2020 19:06:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'MIGRAINE HEADACHES'	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '2'	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'capsule (CAPSULE)'	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'as needed (PRN)'	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:06:51
User entered 'UN UNK 2002'	Dana Finley (b) (4)	15 Aug 2020 19:06:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:06:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:06:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 19:06:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 19:06:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 19:06:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE, PRODUCTSYNONYM: TRUVADA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 19:10:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:10:19
Data point term sent to Coder User entered 'TRUVADA'	System Dana Finley (b) (4)	15 Aug 2020 19:08:58 15 Aug 2020 19:07:58

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'PROPHYLAXIS FOR HIV'	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '200/300'	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'mg (mg)'	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'once daily (QD)'	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:07:58
User entered 'UN UNK 2015'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:07:58

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:07:58
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:07:58

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:07:58

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 19:07:58

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:10:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:10:19
Data point term sent to Coder	System	15 Aug 2020 19:08:58
User entered 'ALLEGRA'	Dana Finley (b) (4)	15 Aug 2020 19:08:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'SEASONAL ALLERGIES'	(b) (4) Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:08:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '180'	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'mg (mg)'	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'as needed (PRN)'	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:27
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:08:51
User entered 'UN UNK 2014'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:08:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:08:51
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 19:08:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 19:08:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 19:08:51

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Aug 2020 19:11:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 19:11:19
Data point term sent to Coder	System	15 Aug 2020 19:09:59
User entered 'GLUCOSAMINE CHONDROITIN'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:09:52
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'NUTRITIONAL SUPPLEMENT'	(b) (4) Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '1500/1200'	Dana Finley (b) (4)	15 Aug 2020 19:09:52
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'mg (mg)'	Dana Finley (b) (4)	15 Aug 2020 19:09:52
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:57:59
User entered empty.	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'once daily (QD)'	Dana Finley (b) (4)	15 Aug 2020 19:09:52
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:57:59
User entered empty.	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:09:52
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:09:52
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:09:52
User entered 'UN UNK 2012'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:09:52
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 19:09:52

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 19:12:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 19:12:19
Data point term sent to Coder	System	15 Aug 2020 19:11:01
User entered 'VITAMIN D3'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:10:40

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'NUTRITIONAL SUPPLEMENT'	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '150'	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'ug (ug)'	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'once daily (QD)'	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:10:40
User entered 'UN UNK 2012'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:10:40

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:10:40
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:10:40

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:10:40

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 19:10:40

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 19:13:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:13:20
Data point term sent to Coder	System	15 Aug 2020 19:12:03
User entered 'ZINC'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:11:21

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'NUTRITIONAL SUPPLEMENT'	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '30'	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'mg (mg)'	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'once daily (QD)'	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:11:21
User entered 'UN UNK 2020'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:11:21

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:11:21
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:11:21

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:11:21

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 19:11:21

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:18:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:18:23
Data point term sent to Coder	System	15 Aug 2020 19:17:11
User entered 'VITAMIN B12'	Dana Finley (b) (4)	15 Aug 2020 19:16:20

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'NUTRITIONAL SUPPLEMENT'	(b) (4) Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:16:20

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:57:59
User entered '1000'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:16:20

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'ug (ug)'	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'once daily (QD)'	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:57:59
User entered empty.	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:16:20

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:41
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:16:20
User entered 'UN UNK 2012'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:16:20

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:16:20
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:16:20

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:16:20

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 19:16:20

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:18:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 19:18:23
Data point term sent to Coder	System	15 Aug 2020 19:17:12
User entered 'VALTREX'	Dana Finley (b) (4)	15 Aug 2020 19:17:02

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'HERPES SIMPLEX VIRUS 2'	(b) (4) Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:17:02

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '500'	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'mg (mg)'	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:57:59
User entered empty.	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:17:02

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'once daily (QD)'	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:57:59
User entered empty.	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:17:02

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:17:02
User entered 'UN UNK 2014'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:17:02

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:17:02
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:17:02

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:17:02

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 19:17:02

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 23:29:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 23:29:21
Data point term sent to Coder	System	15 Aug 2020 19:19:16
User entered 'ASPIRIN'	Dana Finley (b) (4)	15 Aug 2020 19:18:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'PROPHYLAXIS FOR BLOOD CLOTS RELATED TO COVID-19'	(b) (4) Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:18:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '81'	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'mg (mg)'	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 16:57:59
User entered empty.	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:18:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'once daily (QD)'	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Oral (ORAL)'	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 12:47:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 19:18:19
User entered 'UN UNK 2020'	Dana Finley (b) (4) (b) (4)	15 Aug 2020 19:18:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered '0'	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'Yes (Y)'	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered empty.	Dana Finley (b) (4)	15 Aug 2020 19:18:19
	(b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
	(b) (4)	
User entered 'No (N)'	Dana Finley (b) (4)	15 Aug 2020 19:18:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:18:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 19:18:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 19:18:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 23:16:31
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 23:16:31
Data point term sent to Coder	System	19 Oct 2020 23:15:52
User entered 'FLU SHOT'	Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'Yes (Y)'	(b) (4) Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'FLU'	(b) (4) Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered '0.5' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 00:35:27
User entered '1'	Jayasree Krishnankutty (b) (4)	19 Oct 2020 23:15:19
	Triny Cooper (b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 00:35:27
User entered 'Other (OTHER)'	Jayasree Krishnankutty (b) (4)	19 Oct 2020 23:15:19
	Triny Cooper (b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered empty; reason for change Data Entry Error	(b) (4)	16 Dec 2020 00:35:27
User entered 'SHOT'	Jayasree Krishnankutty (b) (4)	19 Oct 2020 23:15:19
	Triny Cooper (b) (4)	

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Jayasree Krishnankutty	16 Dec 2020 00:35:27
User entered 'once (ONCE)'	(b) (4)	
	Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'Once ever year' reason for change:	(b) (4)	
Data Entry Error	Jayasree Krishnankutty	16 Dec 2020 00:35:27
User entered empty.	(b) (4)	
	Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered empty.	(b) (4) Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered '19 Sep 2020'	(b) (4) Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered '0'	(b) (4) Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered '19 Sep 2020'	(b) (4) Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User entered empty.	System	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User entered empty.	System	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:20
User entered empty.	System	19 Oct 2020 23:15:19

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
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.	(b) (4) Coder Import (b) (4) (b) (4)	07 Feb 2021 18:27:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Feb 2021 18:27:45
Data point term sent to Coder	System	07 Feb 2021 18:27:26
User entered 'TYLENOL'	Colleen Jacobsen (b) (4) (b) (4) (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'No (N)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 06:51:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify.' answered with 'Tylenol was taken for a solicited symptom of injection site soreness on the day of injection. Not an AE.' (Site from DM).	Jayasree Krishnankutty (b) (4)	05 Mar 2021 19:33:51
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 detail to the AE eCRF if applicable. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 07:22:03
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' canceled (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 07:21:58
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:21:59
User entered 'PAIN AT INJECTION SITE'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '500'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'mg (mg)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'twice daily (BID)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'Oral (ORAL)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered empty.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '29 Jan 2021'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '0'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'No (N)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 06:51:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate.' answered with 'OL-1 visit was on 29-JAN-2021. Subject got the vaccine that day. Tylenol was taken for the solicited symptom of injection site soreness.' (Site from DM).	Jayasree Krishnankutty (b) (4)	05 Mar 2021 19:35:55
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:22:09
User entered '29 Jan 2021'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'Yes (Y)'	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User entered '2'	System	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User entered '1'	System	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:25
User entered '804 (804)'	System	07 Feb 2021 18:26:42

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
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.	(b) (4) Coder Import (b) (4) (b) (4)	05 Mar 2021 20:21:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 20:21:57
Data point term sent to Coder	System	05 Mar 2021 20:21:08
User entered 'Tylenol'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'Solicited symptoms of injection site soreness and headache'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '500'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'mg (mg)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered empty.	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'four times daily (QID)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered empty.	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'Oral (ORAL)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered empty.	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '26 Feb 2021'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '0'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '26 Feb 2021'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User closed query 'Per DM CLR: Was this medication taken for solicited event= YES. However, note that Solicited ARs are collected on Blinded Phase only per protocol. Review if this should be recorded as an Adverse Event (unsolicited). Update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:15:31
Query 'Per DM CLR: Was this medication taken for solicited event= YES. However, note that Solicited ARs are collected on Blinded Phase only per protocol. Review if this should be recorded as an Adverse Event (unsolicited). Update entry as appropriate. ' answered with 'updated ' (Site from DM).	Sinikka Green (b) (4) (b) (4)	07 Apr 2021 22:38:25
Signature has been broken.	Sinikka Green (b) (4) (b) (4)	07 Apr 2021 22:38:18
User entered 'No (N)' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	07 Apr 2021 22:38:18
User opened query 'Per DM CLR: Was this medication taken for solicited event= YES. However, note that Solicited ARs are collected on Blinded Phase only per protocol. Review if this should be recorded as an Adverse Event (unsolicited). Update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:29:03
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	09 Mar 2021 17:07:55
User entered 'Yes (Y)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User entered '4'	System	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User entered '1'	System	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:30
User entered '804 (804)'	System	05 Mar 2021 20:21:03

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
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.	(b) (4) Coder Import (b) (4) (b) (4)	05 Mar 2021 20:23:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 20:23:01
Data point term sent to Coder	System	05 Mar 2021 20:22:09
User entered 'Tylenol'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'Solicited symptoms of injection site soreness and headache'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '500'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'mg (mg)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered empty.	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'twice daily (BID)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered empty.	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'Oral (ORAL)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered empty.	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '27 Feb 2021'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '0'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered '27 Feb 2021'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User signature succeeded.	Sinikka Green (b) (4)	08 Apr 2021 22:54:39
User closed query 'Per DM CLR: Was this medication taken for solicited event= YES. However, note that Solicited ARs are collected on Blinded Phase only per protocol. Review if this should be recorded as an Adverse Event (unsolicited). Update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:15:36
Signature has been broken.	Sinikka Green (b) (4)	07 Apr 2021 22:38:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Sinikka Green (b) (4)	07 Apr 2021 22:38:36
Query 'Per DM CLR: Was this medication taken for solicited event= YES. However, note that Solicited ARs are collected on Blinded Phase only per protocol. Review if this should be recorded as an Adverse Event (unsolicited). Update entry as appropriate. ' answered with 'updated' (Site from DM).	(b) (4)	07 Apr 2021 22:38:32
User opened query 'Per DM CLR: Was this medication taken for solicited event= YES. However, note that Solicited ARs are collected on Blinded Phase only per protocol. Review if this should be recorded as an Adverse Event (unsolicited). Update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:30:06
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:07:55
User entered 'Yes (Y)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User entered '2'	System	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User entered '1'	System	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:35
User entered '804 (804)'	System	05 Mar 2021 20:21:56

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 07:24:57
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 Mar 2021 07:24:57
Data point term sent to Coder	System	19 Mar 2021 03:22:36
User entered 'Benzonatate'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'Productive cough'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered '200'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'mg (mg)'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered empty.	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'three times daily (TID)'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered empty.	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'Oral (ORAL)'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered empty.	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered '12 Feb 2021'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered '0'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered '15 Feb 2021'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User signature succeeded.	Sinikka Green (b) (4)	23 Mar 2021 15:48:10
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User entered '3'	System	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User entered '1'	System	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:40:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:16:40
User entered '804 (804)'	System	19 Mar 2021 03:22:06

US3382035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:40:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:19:42
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
Signature has been broken.	(b) (4) Colleen Jacobsen (b) (4)	07 Feb 2021 18:27:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	07 Feb 2021 18:27:29
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'No (N)'	(b) (4) Michelle Jackson (b) (4)	28 Sep 2020 14:14:00

US3382035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:40:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	(b) (4)	07 Feb 2021 18:28:34
User entered '14 Aug 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	07 Feb 2021 18:28:34
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	07 Feb 2021 18:28:22
User entered '14 Apr 2020'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:28:22

US3382035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:40:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered 'COVID PCR TEST'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:28:22

US3382035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:40:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Colleen Jacobsen (b) (4)	07 Feb 2021 18:28:22

US3382035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:40:51

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:17:59
	(b) (4)	
User entered empty.	Colleen Jacobsen (b) (4)	07 Feb 2021 18:28:22

US3382035

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:40:51

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered '24 Aug 2020'	(b) (4) Sikhongi Phungwayo (b) (4)	10 Dec 2020 15:57:42

US3382035

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:40:51

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4) Sikhongi Phungwayo (b) (4)	10 Dec 2020 15:57:42

US3382035

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:40:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:57:59
User entered empty.	Sikhongi Phungwayo (b) (4)	10 Dec 2020 15:57:42

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered	System	29 Sep 2020 15:09:39
'USA-US096-2020-MRNA-1273-P301000002'		

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Death

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'Gregg'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'Lucksinger'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered '1900 Cypress Creek Rd'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'Cedar Park'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'TX'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered '78613'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered 'US'	System	29 Sep 2020 15:12:10

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'I'	(b) (4) System	29 Sep 2020 15:12:10

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered	System	29 Sep 2020 15:09:39
'USA-US096-2020-MRNA-1273-P301000002'		

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Death

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'No (N)'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'Gregg'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'Lucksinger'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered '1900 Cypress Creek Rd'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'Cedar Park'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered 'TX'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:12:03
User entered '78613'	System	29 Sep 2020 15:09:39

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered 'US'	System	29 Sep 2020 15:12:10

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:40:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered 'I'	(b) (4) System	29 Sep 2020 15:12:10

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:40:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
User signature succeeded.	(b) (4) Sinikka Green (b) (4)	26 Jan 2021 16:58:10
User entered '29/Sep/2020 15:12'	(b) (4) System	29 Sep 2020 15:12:10

US3382035

Folder: SAE USA-US096-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:40:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	William Smith (b) (4)	19 Apr 2021 20:33:07
	(b) (4)	
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 16:58:10
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 15:12:10