

US3482302 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:44:55

All time stamps listed in this document are displayed in GMT

US3482302

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

[Participant ID](#)

US3482302

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

US3482302

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
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	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 15:40:32

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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) 13 Feb 2021 15:40:32

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Condition	ARTHRITIS IN RIGHT KNEE
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 (3)

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Condition	CATARACT
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3482302

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Condition	CHRONIC KIDNEY DISEASE STAGE 3
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: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Condition	GLAUCOMA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:50 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 09:50
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	186 lb
BMI (<i>xxx.x</i>)	31.01674 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:40:35

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:40:35

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:40:35

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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	True
Specify	RESIDES IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

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

Visit date (dd MMM yyyy)	19 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

What was the date of randomization? (dd MMM yyyy) 19 OCT 2020

What was the participant's randomization number? 190581

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

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) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

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)	19 OCT 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 09:50
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

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)	19 OCT 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 11:30
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

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) 19 OCT 2020

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

Treatment Date and Time (derived) 19 OCT 2020 10:59

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	10:45 (24 HR)
Collection date and time (derived)	19 OCT 2020 10:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Collection date (dd MMM yyyy)			19 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:50	19 OCT 2020 10:50
Nasopharyngeal Swab 2	No		

US3482302

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

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: 09 Jun 2021 17:44:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 11:46

PC Open Date & Time

19 OCT 2020 11:19

PC Close Date & Time

19 OCT 2020 13:49

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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 98.6 °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	19 OCT 2020 19:06
PC Open Date & Time	19 OCT 2020 14:44
PC Close Date & Time	20 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 22:59

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

98.8 °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

21 OCT 2020 19:22

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 20:52

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

23 OCT 2020 19:43

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

24 OCT 2020 19:31

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 19:44

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 11:46

PC Open Date & Time

19 OCT 2020 11:19

PC Close Date & Time

19 OCT 2020 13:49

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 19:07

PC Open Date & Time

19 OCT 2020 14:44

PC Close Date & Time

20 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 23:00

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

21 OCT 2020 19:23

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

22 OCT 2020 20:53

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

23 OCT 2020 19:43

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

24 OCT 2020 19:31

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 OCT 2020 19:44

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

No ☒

Yes ☐

PC Time stamp	19 OCT 2020 11:47
PC Open Date & Time	19 OCT 2020 11:19
PC Close Date & Time	19 OCT 2020 13:49

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

No ☒

Yes ☐

PC Time stamp	19 OCT 2020 19:08
PC Open Date & Time	19 OCT 2020 14:44
PC Close Date & Time	20 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

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 ☒

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 23:01
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

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 ☒

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 19:24
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 3355

EAB) (1725)

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 20:53
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

52 of 3355

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

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 ☒

PRODUCTION RELEASE (v12.003

54 of 3355

EAB) (1725)

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 19:32
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 3355

EAB) (1725)

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 19:45
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3482302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 09:05
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 10:35
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3482302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 16 NOV 2020

What was the treatment time? (00:00-23:59) 10:03 (24 HR)

Treatment Date and Time (derived) 16 NOV 2020 10:03

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

US3482302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 NOV 2020

Collection time (00:00-23:59)

09:35 (24 HR)

Collection date and time (derived)

16 NOV 2020 09:35

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Collection date (dd MMM yyyy)			16 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:44	16 NOV 2020 09:44
Nasopharyngeal Swab 2	No		

US3482302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 NOV 2020 10:40

PC Open Date & Time

16 NOV 2020 10:23

PC Close Date & Time

16 NOV 2020 12:53

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °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	17 NOV 2020 09:48
PC Open Date & Time	16 NOV 2020 13:48
PC Close Date & Time	17 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 NOV 2020 21:32

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 NOV 2020 22:53

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

19 NOV 2020 22:01

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 NOV 2020 22:07

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 NOV 2020 21:34

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 NOV 2020 21:45

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 NOV 2020 10:41

PC Open Date & Time

16 NOV 2020 10:23

PC Close Date & Time

16 NOV 2020 12:53

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 NOV 2020 09:49

PC Open Date & Time

16 NOV 2020 13:48

PC Close Date & Time

17 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 NOV 2020 21:33

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 NOV 2020 22:54

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 NOV 2020 22:01

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 NOV 2020 22:08

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

21 NOV 2020 21:35

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 NOV 2020 21:46

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

No ☒

Yes ☐

PC Time stamp	16 NOV 2020 10:42
PC Open Date & Time	16 NOV 2020 10:23
PC Close Date & Time	16 NOV 2020 12:53

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

16 NOV 2020 13:48

PC Close Date & Time

17 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

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 ☒

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 21:36
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

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 ☒

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	18 NOV 2020 22:54
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

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 ☒

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	19 NOV 2020 22:02
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	20 NOV 2020 22:09
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	21 NOV 2020 21:36
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 21:47
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3482302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:40:32

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

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) _____

US3482302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

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.

US3482302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 DEC 2020
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	14 DEC 2020 09:30

US3482302

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:40:35

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 09:06:14
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 10:34:16
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 10:02:26

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 23:00:31

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 89

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

No ☒

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 21:22:37

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	23 JAN 2021 19:26:55
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 10:09:59

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

28 FEB 2021 01:01:58

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

03 MAR 2021 00:03:40

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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	11 MAR 2021 07:47:18
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 10:47:35

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 06:09:54

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 00:05:16

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 09:35:02

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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	01 MAY 2021 10:23:11
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 208

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 215

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 222

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

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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°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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 292

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

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

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

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

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

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

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	05 SEP 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐ 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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 390

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

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

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

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

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

Date and time of submission

Patient Cloud Open Date & Time	10 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	28 NOV 2021 23:59
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US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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="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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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°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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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°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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐ 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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

27 NOV 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

[Patient Cloud Close Date & Time](#)

04 DEC 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2022 23:59

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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°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 ☐

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2022 00:01
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Patient Cloud Close Date & Time	18 DEC 2022 23:59
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US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

Date and time of submission	
Patient Cloud Open Date & Time	21 DEC 2022 00:01
Patient Cloud Close Date & Time	25 DEC 2022 23:59

US3482302

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:44:55

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 01:02:32

US3482302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Date of Contact	14 JAN 2021
Time of Contact	08:30
Date and Time of Contact (derived)	14 JAN 2021 08:30
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

323 of 3355

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

Date	12 JAN 2021
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	100.4 F
-------------	---------

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

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

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

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

Date	14 JAN 2021
------	-------------

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

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

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

Temperature	99 F
-------------	------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	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 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	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 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

Date	16 JAN 2021
------	-------------

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

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

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

Temperature	99.7 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	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 (6)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	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 14 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

Date	18 JAN 2021
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	100.0 F
-------------	---------

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

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

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

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	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 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 14 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 14 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	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 14 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 14 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 JAN 2021	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	102.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	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 14 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 14 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 14 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 JAN 2021	
Assessment Not Done	False	
O2 Saturation	86 %	
O2 Saturation Units	%	
Temperature	99.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

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Generated On: 09 Jun 2021 17:44:55

	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 14 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 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 14 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	36.6 C	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

Date	23 JAN 2021
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	36.7 C
-------------	--------

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

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

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

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

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Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 JAN 2021	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	36.5 C	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

Date	25 JAN 2021
------	-------------

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

O2 Saturation	93 %
---------------	------

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

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

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

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

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

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

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Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	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 14 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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 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 14 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

	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 14 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:49:52

Generated On: 09 Jun 2021 17:44:55

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"/>

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Date of Visit	14 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	14 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 18:20:52

Generated On: 09 Jun 2021 17:44:55

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 20 JAN 2021

End Date 25 JAN 2021

Oxygen Saturation 86 %

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 14 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 18:20:52

Generated On: 09 Jun 2021 17:44:55

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

21 JAN 2021

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 18:20:52

Generated On: 09 Jun 2021 17:44:55

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒
No ☐

Date of Assessment 21 JAN 2021

Radiographical Evidence Yes ☒
No ☐

Date of Assessment 21 JAN 2021

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

Start Date

End Date

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 JAN 2021
Day 5	Yes	18 JAN 2021
Day 7	Yes	20 JAN 2021
Day 9	No	
Day 14	Yes	27 JAN 2021
Day 21	No	
Day 28	Yes	15 FEB 2021

US3482302

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:23:45

Generated On: 09 Jun 2021 17:44:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 10:04
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482302

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3482302

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 JAN 2021

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 22:34:25

Generated On: 09 Jun 2021 17:44:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	SICKD28

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 22:34:25

Generated On: 09 Jun 2021 17:44:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	09:37 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 09:37
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 22:34:25

Generated On: 09 Jun 2021 17:44:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3482302

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Mar 2021 22:34:25

Generated On: 09 Jun 2021 17:44:55

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 FEB 2021

US3482302

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3482302

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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>)	14 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

US3482302

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

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

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	14:47 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 14:47
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	15:36 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 15:36
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3482302

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3482302

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

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) 19 FEB 2021

What was the treatment time? (00:00-23:59) 15:05 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 15:05

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

US3482302

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	08:40 (24 HR)
Collection date and time (derived)	14 JAN 2021 08:40

US3482302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	08:45
Collection Date and Time (derived)	14 JAN 2021 08:45

US3482302

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 MAR 2021
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 10:04
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 MAR 2021
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 11:15
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3482302

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 MAR 2021

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

US3482302

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

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) 16 MAR 2021

What was the treatment time? (00:00-23:59) 10:42 (24 HR)

Treatment Date and Time (derived) 16 MAR 2021 10:42

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

What was the frequency of the study treatment dosing? ONCE

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

US3482302

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:35:55

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482302

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482302

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

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) _____

US3482302

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

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.

US3482302

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 APR 2021
Collection time (00:00-23:59)	10:06 (24 HR)
Collection date and time (derived)	12 APR 2021 10:06

US3482302

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:26:48

Generated On: 09 Jun 2021 17:44:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

AEID	USA-US106-2021-MRNA-1273-P30 1000008
Adverse event	COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	11 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	25 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

SUBJECT BEING FOLLOWED
FOR ILLNESS VISIT VIA
TELEMEDICINE AFTER
POSITIVE COVID TEST DURING
ILLNESS VISIT. SUBJECT
NOTED TO HAVE DECREASED
O2 SATS (86-88%). SEND FOR
CLINICAL EVALUATION, SENT
TO ER WHERE HE WAS
ADMITTED AND PLACED ON
SUPPLEMENTAL OXYGEN.
AWAITING MEDICAL RECORDS
FOR MORE INFORMATION.
RT-PCR TEST DONE ON
21JAN2021 DURING THIS
ADMISSION, POSITIVE.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3482302

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

AEID	USA-US106-2021-MRNA-1273-P30 1000011
Adverse event	ACUTE RENAL FAILURE SUPERIMPOSED ON CHRONIC KIDNEY DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

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

US3482302

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

SUBJECT WAS ADMITTED TO THE EMERGENCY DEPARTMENT ON 2/1/2021 WITH DECREASED APPETITE AND NAUSEA. HE STATES THAT HE WAS TAKING ASCORBIC ACID THAT WAS PRESCRIBED FROM HIS PREVIOUS HOSPITALIZATION THAT WAS MAKING HIM NAUSEATED. WHILE IN THE EMERGENCY DEPARTMENT, THE SUBJECT UNDERWENT LABS. BLOOD GLUCOSE WAS FOUND TO BE ELEVATED (359) WITH AN HGBA1C OF 8.5 IN ADDITION TO AN ELEVATED MAGNESIUM (2.7) AND AN ELEVATED POTASSIUM (5.2). HE ALSO HAD HYPONATREMIA (NA 131). HE WAS STARTED ON IV NS VIA BOLUS AND INSULIN, WHICH IS DOCUMENTED IN HIS CON MEDS. A CT OF THE ABDOMEN AND PELVIS DONE ON 2/1/2021 SHOWED NO ACUTE ABNORMALITIES IN HIS ABDOMEN. HE WAS STARTED ON OMEPRAZOLE FOR HIS ACUTE GI SYMPTOMS AND SODIUM CHLORIDE TABLETS TO TREAT HIS HYPONATREMIA. NO DOCUMENTED ANTI-EMETICS WERE ADMINISTERED PER HIS MEDICAL RECORDS. ALL MEDICATIONS FROM HIS HOSPITALIZATION ARE INCLUDED IN HIS CON MED LOG AND HIS ADMITTING DIAGNOSES ARE RECORDED AS SEPARATE AES.

Serious Adverse Event Derived (CSA Programming Field Only)

1

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

AEID	
Adverse event	DIABETES TYPE II, NEW ONSET
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

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 checked="" 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	BLOOD GLUCOSE RECORDINGS FROM 290-359, HGB A1C 8.5 DRAWN ON 2/1/2021.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

AEID

Adverse event

HYPONATREMIA

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)

01 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)

03 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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒
Related ☐
Not Applicable ☐

Relationship to Study Procedure Not Related ☒
Related ☐
Not Applicable ☐

Action taken with investigational product None ☐
Dose Delayed ☒
Investigational Product ☐
Withdrawn ☐
Not Applicable ☐

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal ☐
Not Recovered/Not Resolved ☐
Recovered/Resolved ☒
Recovered/Resolved with Sequelae ☐
Recovering/Resolving ☐
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative SUBJECT FOUND TO HAVE SODIUM LEVEL OF 131 ON ADMISSION LABS, TREATED WITH SODIUM CHLORIDE TABLET, IV FLUIDS.

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 1

Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 16:23:44

Generated On: 09 Jun 2021 17:44:55

AEID	
Adverse event	HYPERKALEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

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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 checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 16:23:44

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AEID

Adverse event

HYPERMAGNESEMIA

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)

01 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)

03 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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 16:23:44

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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 checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 08 Apr 2021 16:23:44

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AEID	USA-US106-2021-MRNA-1273-P30 1000011
Adverse event	INTRACTABLE NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 08 Apr 2021 16:23:44

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	RELATED TO SAE FOR ACUTE RENAL FAILURE, SPLIT INTO TWO SEPARATE DIAGNOSES PER QUERY RESOLUTION.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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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) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication LATANOPROST 0.005%

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP/EYE

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) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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 2017	
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) 17 Apr 2021 03:11:51

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Name of Medication DORZALOMIDE 22.3 MG/
TIMOLOLOL 6.8 MG/ML

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 2

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

If dose unit is Other, specify DROPS/EYE

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 17 Apr 2021 03:11:51

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	Intraocular	<input checked="" type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 17 Apr 2021 03:11:51

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Name of Medication DICLOFENAC

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS IN KNEE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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 2016	
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 (6)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication ZINC SULFATE

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 220

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) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)	22 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)	30 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒
No ☐

Indication PEPTIC ULCER DISEASE
PROPHYLAXIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Apr 2021 03:11:51

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	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)	22 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)		24 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication ASCORBIC ACID

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)	22 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)		30 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication DEXMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 6

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 (9)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	21 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 21 JAN 2021		
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 (10)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication DEXMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	01 FEB 2021	
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 (11)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication FEVER

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)	21 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)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication AZYTHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)	21 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)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication VTE PROPHYLAXIS

Dose per administration 40

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 (13)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)	22 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)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID 19

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 (14)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	22 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	25 JAN 2021	
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 (15)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication COVID 19 RELATED
PNEUMONIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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 checked="" 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)	21 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)		24 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication HYPERGLYCEMIA FROM
NEWLY DIAGNOSED DIABETES
TYPE II

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)		03 FEB 2021
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)		2
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 (17)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication VTE PROPHYLAXIS

Dose per administration 40

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 (17)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)	01 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)	03 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication HUMALOG INSULIN

Prophylaxis Yes ☐
No ☒

Indication HYPERGLYCEMIA FROM
NEWLY DIAGNOSED DIABETES
TYPE II

Dose per administration 2

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)	01 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)		03 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
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="checkbox"/>

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication GERD PROPHYLAXIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	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)		04 FEB 2021
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"/>

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPONATREMIA

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	03 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication KETOROLAC TROMETHAMINE

Prophylaxis Yes ☐
No ☒

Indication LEFT EYE CATARACT
REMOVAL

Dose per administration 1

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

If dose unit is Other, specify GTT

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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US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OTIC	
Start date (dd MMM yyyy)	29 MAR 2021	
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Name of Medication DIFLUPREDNATE

Prophylaxis Yes ☐
No ☒

Indication LEFT EYE CATARACT
REMOVAL

Dose per administration 1

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

If dose unit is Other, specify GTT

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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US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OTIC	
Start date (dd MMM yyyy)	29 MAR 2021	
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 22:34:25

Generated On: 09 Jun 2021 17:44:55

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 17 Apr 2021 03:11:51

Generated On: 09 Jun 2021 17:44:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 JAN 2021	LUNG PERFUSION SCAN	Diagnostic	
21 JAN 2021	X-RAY CHEST	Diagnostic	
22 JAN 2021	CONVALESCENT PLASMA INFUSION	Adverse Event	
21 JAN 2021	SUPPLEMENTAL OXYGEN	Adverse Event	
29 MAR 2021	LEFT EYE CATARACT REMOVAL	Medical History	

US3482302

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:44:55

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3482302

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:44:55

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 ☐

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/JAN/2021 10:41
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/JAN/2021 11:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/FEB/2021 10:02
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/FEB/2021 09:36
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	18/FEB/2021 12:12
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/MAR/2021 13:44
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Data signed: (b) (4) 01 Apr 2021 23:35:56

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/MAR/2021 12:33
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	17/FEB/2021 10:10
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	18/FEB/2021 11:47
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	22/MAR/2021 06:32
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	23/MAR/2021 08:17
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	23/MAR/2021 09:36
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	24/MAR/2021 12:12
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (7)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	25/MAR/2021 11:09
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (8)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	25/MAR/2021 12:20
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (9)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	29/MAR/2021 13:08
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

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (10)

Data signed: (b) (4) 08 Apr 2021 16:23:46

Generated On: 09 Jun 2021 17:44:55

SAEID	USA-US106-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	06/APR/2021 12:22
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

US3482302 (Prod: Hope Clinic of The Emory Vaccine Center)

US3482302

Form: Participant Creation

Generated On: 09 Jun 2021 17:44:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'US3482302'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 13:28:39

US3482302

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	19 Oct 2020 15:07:50

US3482302

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 13:28:40

US3482302

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Clinic (Clinic)'	Sarah Bechnak (b) (4)	19 Oct 2020 15:07:50

US3482302

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'SCRN'	System	19 Oct 2020 15:07:50

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 13:28:41

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered '73'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User entered 'YEARS'	System	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User entered '73'	System	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered 'Male (M)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:12
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:00:34

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:55
User entered '19 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User entered 'Oct 2020'	System	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User entered '2020'	System	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:55
User entered 'Amendment 4 (4)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:55
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:55
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:55
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:55
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:44:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 13:28:40

US3482302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:05:34
User entered 'I'	System	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:25:03
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:03

US3482302

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:44:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:00:43

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:03:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:03:33
Data point term sent to Coder	System	19 Oct 2020 16:02:41
User entered 'Hypertension'	Sarah Bechnak (b) (4)	19 Oct 2020 16:02:17
	(b) (4)	

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'un UNK 1996'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:02:17

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:02:17

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:02:17

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:02:17

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:02:17

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'Jan 1996'	System	19 Oct 2020 16:02:17

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered '1996'	System	19 Oct 2020 16:02:17

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:02:17

US3482302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:02:17

US3482302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:03:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:03:33
Data point term sent to Coder	System	19 Oct 2020 16:02:41
User entered 'Arthritis in right knee'	Sarah Bechnak (b) (4)	19 Oct 2020 16:02:38
	(b) (4)	

US3482302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'un UNK 2012'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:02:38

US3482302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:02:38

US3482302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:02:38

US3482302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:02:38

US3482302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	Sarah Bechnak (b) (4)	19 Oct 2020 16:02:38

US3482302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'Jan 2012'	System	19 Oct 2020 16:02:38

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered '2012'	System	19 Oct 2020 16:02:38

US3482302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:02:38

US3482302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:02:38

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:04:40
Data point term sent to Coder	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 16:03:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 16:03:34
User entered 'Cataract' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Oct 2020 16:03:08
	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:08
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	19 Oct 2020 16:03:34
User entered 'un UNK 2017' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:34
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	19 Oct 2020 16:03:08
User entered empty.	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:08
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:03:08

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
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	19 Oct 2020 16:03:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Oct 2020 16:03:08
	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:08
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:03:08

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:08

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'Jan 2017'	System	19 Oct 2020 16:03:34
User entered empty.	System	19 Oct 2020 16:03:08

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered '2017'	System	19 Oct 2020 16:03:34
User entered empty.	System	19 Oct 2020 16:03:08

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:03:08

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:03:08

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 17:34:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 17:34:20
Data point term sent to Coder	System	18 Dec 2020 16:41:26
User entered 'CHRONIC KIDNEY DISEASE STAGE 3' reason for change: Per Query Resolution	Sarah Bechnak (b) (4)	18 Dec 2020 16:41:04
Coding entries removed.	Sarah Bechnak (b) (4)	18 Dec 2020 16:40:41
User entered 'Chronic Kidney Disease Stage 39i' reason for change: Per Query Resolution	Sarah Bechnak (b) (4)	18 Dec 2020 16:40:41
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal disorders NEC, PT: Renal disorder, LLT: Kidney disorder - version MedDRA\23.0.	Coder Import (b) (4)	22 Nov 2020 23:35:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Nov 2020 23:35:02
Data point term sent to Coder	System	13 Nov 2020 17:44:10
User closed query 'Requery: For coding purposes, for term ABNORMAL KIDNEY, if unknown, please update the term to report this. (i.e. ABNORMAL KIDNEY(UNKNOWN))' (Site from System).	System	13 Nov 2020 17:43:47
Query 'Requery: For coding purposes, for term ABNORMAL KIDNEY, if unknown, please update the term to report this. (i.e. ABNORMAL KIDNEY(UNKNOWN))' answered with 'DONE' (Site from System).	Sarah Bechnak (b) (4)	13 Nov 2020 17:43:47
User entered 'ABNORMAL KIDNEY (UNKNOWN)' reason for change: Per Query Resolution	Sarah Bechnak (b) (4)	13 Nov 2020 17:43:21
User opened query 'Requery: For coding purposes, for term ABNORMAL KIDNEY, if unknown, please update the term to report this. (i.e. ABNORMAL KIDNEY(UNKNOWN))' (Site from System).	Coder Import (b) (4)	10 Nov 2020 11:09:29

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	06 Nov 2020 14:27:37
User closed query 'Requery: For coding purposes, for term ABNORMAL KIDNEY, if unknown, please update the term to report this.' (Site from System).	System	06 Nov 2020 14:27:00
Query 'Requery: For coding purposes, for term ABNORMAL KIDNEY, if unknown, please update the term to report this.' answered with 'Unknown abnormality. Subject does not know what the abnormality is but will follow up with nephrologist soon.' (Site from System).	Sarah Bechnak (b) (4)	06 Nov 2020 14:27:00
User opened query 'Requery: For coding purposes, for term ABNORMAL KIDNEY, if unknown, please update the term to report this.' (Site from System).	Coder Import (b) (4)	25 Oct 2020 14:07:24
Data point term sent to Coder	System	23 Oct 2020 21:17:08
User closed query 'For coding purposes, for term ABNORMAL KIDNEY please clarify/provide more information. Is this Renal agenesis, Renal malposition, Kidney malformation or something else. Please update the term with your response' (Site from System).	System	23 Oct 2020 21:16:58
Query 'For coding purposes, for term ABNORMAL KIDNEY please clarify/provide more information. Is this Renal agenesis, Renal malposition, Kidney malformation or something else. Please update the term with your response' answered with 'PARTICIPANT UNSURE OF FURTHER DIAGNOSIS. HAS APPT FOR FURTHER FOLLOW UP.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 21:16:58
User opened query 'For coding purposes, for term ABNORMAL KIDNEY please clarify/provide more information. Is this Renal agenesis, Renal malposition, Kidney malformation or something else. Please update the term with your response' (Site from System).	Coder Import (b) (4)	19 Oct 2020 18:49:21
Data point term sent to Coder	System	19 Oct 2020 16:04:43
User entered 'Abnormal kidney'	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:51

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'un UNK 2014'	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:51

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:51

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:03:51

US3482302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:03:51

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	Sarah Bechnak (b) (4)	19 Oct 2020 16:03:51

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'Jan 2014'	System	19 Oct 2020 16:03:51

US3482302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered '2014'	System	19 Oct 2020 16:03:51

US3482302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:03:51

US3482302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:03:51

US3482302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:05:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:05:41
Data point term sent to Coder	System	19 Oct 2020 16:04:43
User entered 'Glaucoma'	Sarah Bechnak (b) (4)	19 Oct 2020 16:04:08
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'un UNK 2017'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:04:08

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	Sarah Bechnak (b) (4)	19 Oct 2020 16:04:08

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:04:08

US3482302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:04:08

US3482302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '0'	Sarah Bechnak (b) (4)	19 Oct 2020 16:04:08

US3482302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'Jan 2017'	System	19 Oct 2020 16:04:08

US3482302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered '2017'	System	19 Oct 2020 16:04:08

US3482302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:04:08

US3482302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered empty.	System	19 Oct 2020 16:04:08

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 Oct 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '09:50'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered '19 Oct 2020 09:50'	System	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '65' in	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:05:04
DataPoint set to visible.	(b) (4) System	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '186' lb	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:05:04
DataPoint set to visible.	(b) (4) System	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered '31.01674'	System	19 Oct 2020 16:05:04
DataPoint set to visible.	System	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'kg/m2'	System	19 Oct 2020 16:05:04
DataPoint set to visible.	System	19 Oct 2020 15:08:19

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'bpm'	System	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'breaths/min'	System	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'mmHg'	System	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User entered 'mmHg'	System	19 Oct 2020 16:05:04

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06

US3482302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06

US3482302

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:05:19

US3482302

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 Oct 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:05:19

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

[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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

[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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

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 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'I'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'I'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:06:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:36:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'resides in a community with ongoing person to person transmission.'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:03

US3482302

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 15:07:09

US3482302

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 Oct 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:07:09

US3482302

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[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 15:05:37
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:07:09

US3482302

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'VISIT1'	System	19 Oct 2020 15:07:09

US3482302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 14:29:01

US3482302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '190581'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 14:29:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:55

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 14:29:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:55

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 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:07:28

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:55

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 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:07:28

US3482302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:55

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:07:28

US3482302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:07:28

US3482302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:07:28

US3482302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:55

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:06:09
DataPoint set to visible.	(b) (4) System	19 Oct 2020 15:08:19

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 Oct 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '09:50'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered '19 Oct 2020 09:50'	System	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:12
User entered '98.2' F reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:12
	(b) (4)	
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:12
User entered '84' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'bpm'	System	19 Oct 2020 16:07:12
User entered empty.	System	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:12
User entered '16' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'breaths/min'	System	19 Oct 2020 16:07:12
User entered empty.	System	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:12
User entered '143' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'mmHg'	System	19 Oct 2020 16:07:12
User entered empty.	System	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:12
User entered '86' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'mmHg'	System	19 Oct 2020 16:07:12
User entered empty.	System	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 Oct 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '11:30'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered '19 Oct 2020 11:30'	System	19 Oct 2020 16:06:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:44
User entered '97.4' F reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:44
	(b) (4)	
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:44
User entered '64' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'bpm'	System	19 Oct 2020 16:07:44
User entered empty.	System	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:44
User entered '16' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'breaths/min'	System	19 Oct 2020 16:07:44
User entered empty.	System	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:44
User entered '145' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'mmHg'	System	19 Oct 2020 16:07:44
User entered empty.	System	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:40:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:07:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:07:44
User entered '74' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Oct 2020 16:07:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:06:38
User entered empty.	System	19 Oct 2020 16:06:38
	Sarah Bechnak (b) (4)	19 Oct 2020 16:06:38
	(b) (4)	

US3482302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'mmHg'	System	19 Oct 2020 16:07:44
User entered empty.	System	19 Oct 2020 16:06:38

US3482302

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:07:53

US3482302

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:07:53

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:41:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:41:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

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 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:41:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'MRNA-1273 OR PLACEBO'	System	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:41:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 Oct 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:41:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '10:59'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered '19 Oct 2020 10:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:41:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:41:13
User entered 'ONCE'	System	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'INTRAMUSCULAR'	System	19 Oct 2020 15:08:48

US3482302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:08:30

US3482302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:08:30
	(b) (4)	

US3482302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '10:45'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:08:30

US3482302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered '19 Oct 2020 10:45'	System	19 Oct 2020 16:08:30

US3482302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:44:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '19 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:11:40

US3482302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:11:40

US3482302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:11:40

US3482302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '10:50'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:11:40

US3482302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered '19 Oct 2020 10:50'	System	19 Oct 2020 16:11:40

US3482302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:11:40

US3482302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:11:40

US3482302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:11:40

US3482302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered empty.	System	19 Oct 2020 16:11:40

US3482302

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:12:05

US3482302

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'I'	System	19 Oct 2020 16:12:05

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:45:28', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '68764fcf-c71c-4b35-93d9-a1ad49dcd1d'	System	19 Oct 2020 15:46:11
User entered 'Yes (Y)'	System	19 Oct 2020 15:46:11

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:45:39', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '68764fcf-c71c-4b35-93d9-a1ad49dcd1d'	System	19 Oct 2020 15:46:11
User entered '97.4'	System	19 Oct 2020 15:46:11

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:45:51', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '68764fcf-c71c-4b35-93d9-a1ad49dcd1d'	System	19 Oct 2020 15:46:11
User entered 'No (N)'	System	19 Oct 2020 15:46:11

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:46:06', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '68764fcf-c71c-4b35-93d9-a1ad49dced1d'	System	19 Oct 2020 15:46:11
User entered '19 Oct 2020 11:46'	System	19 Oct 2020 15:46:11

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Oct 2020 11:19'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Oct 2020 13:49'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:05:44', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd028debd-ed07-4969-b49a-b3de73ec8de6'	System	19 Oct 2020 23:06:50
User entered 'Yes (Y)'	System	19 Oct 2020 23:06:50

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:05:53', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd028debd-ed07-4969-b49a-b3de73ec8de6'	System	19 Oct 2020 23:06:50
User entered '98.6'	System	19 Oct 2020 23:06:50

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:06:40', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd028debd-ed07-4969-b49a-b3de73ec8de6'	System	19 Oct 2020 23:06:50
User entered 'No (N)'	System	19 Oct 2020 23:06:50

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:06:48', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd028debd-ed07-4969-b49a-b3de73ec8de6'	System	19 Oct 2020 23:06:50
User entered '19 Oct 2020 19:06'	System	19 Oct 2020 23:06:50

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Oct 2020 14:44'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 2'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T22:58:24', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '6a0c202c-290c-4ff5-ae6c-d0f5715e7047'	System	21 Oct 2020 02:59:17
User entered 'Yes (Y)'	System	21 Oct 2020 02:59:17

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T22:58:34', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '6a0c202c-290c-4ff5-ae6c-d0f5715e7047'	System	21 Oct 2020 02:59:17
User entered '97.8'	System	21 Oct 2020 02:59:17

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T22:58:39', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '6a0c202c-290c-4ff5-ae6c-d0f5715e7047'	System	21 Oct 2020 02:59:17
User entered 'No (N)'	System	21 Oct 2020 02:59:17

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T22:59:14', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '6a0c202c-290c-4ff5-ae6c-d0f5715e7047'	System	21 Oct 2020 02:59:17
User entered '20 Oct 2020 22:59'	System	21 Oct 2020 02:59:17

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 3'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:21:35', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f775d601-3830-434f-8228-5690e36d0570'	System	21 Oct 2020 23:22:08
User entered 'Yes (Y)'	System	21 Oct 2020 23:22:08

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:21:46', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f775d601-3830-434f-8228-5690e36d0570'	System	21 Oct 2020 23:22:08
User entered '98.8'	System	21 Oct 2020 23:22:08

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:21:50', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f775d601-3830-434f-8228-5690e36d0570'	System	21 Oct 2020 23:22:08
User entered 'No (N)'	System	21 Oct 2020 23:22:08

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:22:05', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f775d601-3830-434f-8228-5690e36d0570'	System	21 Oct 2020 23:22:08
User entered '21 Oct 2020 19:22'	System	21 Oct 2020 23:22:08

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 4'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:52:15', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9b8703a2-f9b9-4393-a9f6-bce1ba726f85'	System	23 Oct 2020 00:52:41
User entered 'Yes (Y)'	System	23 Oct 2020 00:52:41

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:52:26', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9b8703a2-f9b9-4393-a9f6-bce1ba726f85'	System	23 Oct 2020 00:52:41
User entered '98.1'	System	23 Oct 2020 00:52:41

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:52:31', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9b8703a2-f9b9-4393-a9f6-bce1ba726f85'	System	23 Oct 2020 00:52:41
User entered 'No (N)'	System	23 Oct 2020 00:52:41

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:52:35', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9b8703a2-f9b9-4393-a9f6-bce1ba726f85'	System	23 Oct 2020 00:52:41
User entered '22 Oct 2020 20:52'	System	23 Oct 2020 00:52:41

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 5'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:42:55', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c436ca19-7d19-45c5-b374-0194bf030bea'	System	23 Oct 2020 23:43:22
User entered 'Yes (Y)'	System	23 Oct 2020 23:43:22

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:43:04', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c436ca19-7d19-45c5-b374-0194bf030bea'	System	23 Oct 2020 23:43:22
User entered '98.2'	System	23 Oct 2020 23:43:22

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:43:12', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c436ca19-7d19-45c5-b374-0194bf030bea'	System	23 Oct 2020 23:43:22
User entered 'No (N)'	System	23 Oct 2020 23:43:22

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:43:17', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c436ca19-7d19-45c5-b374-0194bf030bea'	System	23 Oct 2020 23:43:22
User entered '23 Oct 2020 19:43'	System	23 Oct 2020 23:43:22

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 6'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:30:38', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '81b9b03d-b117-4f72-a8ec-893226f5b899'	System	24 Oct 2020 23:31:06
User entered 'Yes (Y)'	System	24 Oct 2020 23:31:06

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:30:49', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '81b9b03d-b117-4f72-a8ec-893226f5b899'	System	24 Oct 2020 23:31:06
User entered '98.8'	System	24 Oct 2020 23:31:06

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:30:57', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '81b9b03d-b117-4f72-a8ec-893226f5b899'	System	24 Oct 2020 23:31:06
User entered 'No (N)'	System	24 Oct 2020 23:31:06

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:01', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '81b9b03d-b117-4f72-a8ec-893226f5b899'	System	24 Oct 2020 23:31:06
User entered '24 Oct 2020 19:31'	System	24 Oct 2020 23:31:06

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 7'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:43:41', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f22aa778-eb1a-4b72-9dd9-0b50d65f6a79'	System	25 Oct 2020 23:44:07
User entered 'Yes (Y)'	System	25 Oct 2020 23:44:07

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:43:55', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f22aa778-eb1a-4b72-9dd9-0b50d65f6a79'	System	25 Oct 2020 23:44:07
User entered '98.4'	System	25 Oct 2020 23:44:07

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:43:59', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f22aa778-eb1a-4b72-9dd9-0b50d65f6a79'	System	25 Oct 2020 23:44:07
User entered 'No (N)'	System	25 Oct 2020 23:44:07

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:04', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f22aa778-eb1a-4b72-9dd9-0b50d65f6a79'	System	25 Oct 2020 23:44:07
User entered '25 Oct 2020 19:44'	System	25 Oct 2020 23:44:07

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:46:16', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7f2f5fde-c18a-46e5-8208-3c52d515a042'	System	19 Oct 2020 15:47:04
User entered 'None (1)'	System	19 Oct 2020 15:47:04

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:46:33', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7f2f5fde-c18a-46e5-8208-3c52d515a042'	System	19 Oct 2020 15:47:04
User entered 'No (N)'	System	19 Oct 2020 15:47:04

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:46:38', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7f2f5fde-c18a-46e5-8208-3c52d515a042'	System	19 Oct 2020 15:47:04
User entered 'No (N)'	System	19 Oct 2020 15:47:04

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:46:49', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7f2f5fde-c18a-46e5-8208-3c52d515a042'	System	19 Oct 2020 15:47:04
User entered 'None (1)'	System	19 Oct 2020 15:47:04

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:46:55', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7f2f5fde-c18a-46e5-8208-3c52d515a042'	System	19 Oct 2020 15:47:04
User entered '19 Oct 2020 11:46'	System	19 Oct 2020 15:47:04

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Oct 2020 11:19'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Oct 2020 13:49'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:07:07', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '25a8aa95-66d1-4176-b0e3-a3da73d8b627'	System	19 Oct 2020 23:07:39
User entered 'None (1)'	System	19 Oct 2020 23:07:39

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:07:12', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '25a8aa95-66d1-4176-b0e3-a3da73d8b627'	System	19 Oct 2020 23:07:39
User entered 'No (N)'	System	19 Oct 2020 23:07:39

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:07:16', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '25a8aa95-66d1-4176-b0e3-a3da73d8b627'	System	19 Oct 2020 23:07:39
User entered 'No (N)'	System	19 Oct 2020 23:07:39

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:07:24', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '25a8aa95-66d1-4176-b0e3-a3da73d8b627'	System	19 Oct 2020 23:07:39
User entered 'None (1)'	System	19 Oct 2020 23:07:39

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:07:34', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '25a8aa95-66d1-4176-b0e3-a3da73d8b627'	System	19 Oct 2020 23:07:39
User entered '19 Oct 2020 19:07'	System	19 Oct 2020 23:07:39

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Oct 2020 14:44'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 2'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T22:59:35', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'a2d27e00-4a3d-4331-b85a-a8a42978b77f'	System	21 Oct 2020 03:00:10
User entered 'None (1)'	System	21 Oct 2020 03:00:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T22:59:41', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'a2d27e00-4a3d-4331-b85a-a8a42978b77f'	System	21 Oct 2020 03:00:10
User entered 'No (N)'	System	21 Oct 2020 03:00:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T22:59:47', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'a2d27e00-4a3d-4331-b85a-a8a42978b77f'	System	21 Oct 2020 03:00:10
User entered 'No (N)'	System	21 Oct 2020 03:00:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:00:01', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'a2d27e00-4a3d-4331-b85a-a8a42978b77f'	System	21 Oct 2020 03:00:10
User entered 'None (1)'	System	21 Oct 2020 03:00:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:00:07', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'a2d27e00-4a3d-4331-b85a-a8a42978b77f'	System	21 Oct 2020 03:00:10
User entered '20 Oct 2020 23:00'	System	21 Oct 2020 03:00:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 3'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:22:16', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5277373a-a94f-4791-b391-b83d804fde4a'	System	21 Oct 2020 23:23:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	21 Oct 2020 23:23:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:22:24', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5277373a-a94f-4791-b391-b83d804fde4a'	System	21 Oct 2020 23:23:40
User entered 'No (N)'	System	21 Oct 2020 23:23:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:22:28', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5277373a-a94f-4791-b391-b83d804fde4a'	System	21 Oct 2020 23:23:40
User entered 'No (N)'	System	21 Oct 2020 23:23:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:23:21', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5277373a-a94f-4791-b391-b83d804fde4a'	System	21 Oct 2020 23:23:40
User entered 'None (1)'	System	21 Oct 2020 23:23:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:23:37', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5277373a-a94f-4791-b391-b83d804fde4a'	System	21 Oct 2020 23:23:40
User entered '21 Oct 2020 19:23'	System	21 Oct 2020 23:23:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 4'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:52:46', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '846b916e-1680-4df5-82e2-693fccfcb765'	System	23 Oct 2020 00:53:10
User entered 'None (1)'	System	23 Oct 2020 00:53:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:52:52', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '846b916e-1680-4df5-82e2-693fccfcb765'	System	23 Oct 2020 00:53:10
User entered 'No (N)'	System	23 Oct 2020 00:53:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:52:55', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '846b916e-1680-4df5-82e2-693fccfcb765'	System	23 Oct 2020 00:53:10
User entered 'No (N)'	System	23 Oct 2020 00:53:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '846b916e-1680-4df5-82e2-693fccfcb765'	System	23 Oct 2020 00:53:10
User entered 'None (1)'	System	23 Oct 2020 00:53:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:05', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '846b916e-1680-4df5-82e2-693fccfcb765'	System	23 Oct 2020 00:53:10
User entered '22 Oct 2020 20:53'	System	23 Oct 2020 00:53:10

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 5'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:43:32', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '999fbe2a-3469-498f-bf5f-a40c7fb2bcb6'	System	23 Oct 2020 23:44:02
User entered 'None (1)'	System	23 Oct 2020 23:44:02

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:43:42', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '999fbe2a-3469-498f-bf5f-a40c7fb2bcb6'	System	23 Oct 2020 23:44:02
User entered 'No (N)'	System	23 Oct 2020 23:44:02

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:43:47', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '999fbe2a-3469-498f-bf5f-a40c7fb2bcb6'	System	23 Oct 2020 23:44:02
User entered 'No (N)'	System	23 Oct 2020 23:44:02

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:43:52', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '999fbe2a-3469-498f-bf5f-a40c7fb2bcb6'	System	23 Oct 2020 23:44:02
User entered 'None (1)'	System	23 Oct 2020 23:44:02

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:43:59', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '999fbe2a-3469-498f-bf5f-a40c7fb2bcb6'	System	23 Oct 2020 23:44:02
User entered '23 Oct 2020 19:43'	System	23 Oct 2020 23:44:02

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 6'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:11', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '67599893-f3fe-45ef-b8ea-9d97b29ea007'	System	24 Oct 2020 23:31:40
User entered 'None (1)'	System	24 Oct 2020 23:31:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:15', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '67599893-f3fe-45ef-b8ea-9d97b29ea007'	System	24 Oct 2020 23:31:40
User entered 'No (N)'	System	24 Oct 2020 23:31:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:22', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '67599893-f3fe-45ef-b8ea-9d97b29ea007'	System	24 Oct 2020 23:31:40
User entered 'No (N)'	System	24 Oct 2020 23:31:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:35', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '67599893-f3fe-45ef-b8ea-9d97b29ea007'	System	24 Oct 2020 23:31:40
User entered 'None (1)'	System	24 Oct 2020 23:31:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:38', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '67599893-f3fe-45ef-b8ea-9d97b29ea007'	System	24 Oct 2020 23:31:40
User entered '24 Oct 2020 19:31'	System	24 Oct 2020 23:31:40

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 7'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:13', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '907eea95-1b8b-4aed-89fb-c3907868d55e'	System	25 Oct 2020 23:44:38
User entered 'None (1)'	System	25 Oct 2020 23:44:38

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:17', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '907eea95-1b8b-4aed-89fb-c3907868d55e'	System	25 Oct 2020 23:44:38
User entered 'No (N)'	System	25 Oct 2020 23:44:38

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:21', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '907eea95-1b8b-4aed-89fb-c3907868d55e'	System	25 Oct 2020 23:44:38
User entered 'No (N)'	System	25 Oct 2020 23:44:38

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:24', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '907eea95-1b8b-4aed-89fb-c3907868d55e'	System	25 Oct 2020 23:44:38
User entered 'None (1)'	System	25 Oct 2020 23:44:38

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:33', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '907eea95-1b8b-4aed-89fb-c3907868d55e'	System	25 Oct 2020 23:44:38
User entered '25 Oct 2020 19:44'	System	25 Oct 2020 23:44:38

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:47:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c3ccf3db-eeef-4028-995a-ea08b188e0aa'	System	19 Oct 2020 15:47:50
User entered 'None (0)'	System	19 Oct 2020 15:47:50

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:47:06', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c3ccf3db-eeef-4028-995a-ea08b188e0aa'	System	19 Oct 2020 15:47:50
User entered 'None (0)'	System	19 Oct 2020 15:47:50

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:47:10', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c3ccf3db-eeef-4028-995a-ea08b188e0aa'	System	19 Oct 2020 15:47:50
User entered 'None (0)'	System	19 Oct 2020 15:47:50

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:47:15', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c3ccf3db-eeef-4028-995a-ea08b188e0aa'	System	19 Oct 2020 15:47:50
User entered 'None (0)'	System	19 Oct 2020 15:47:50

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:47:17', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c3ccf3db-eecf-4028-995a-ea08b188e0aa'	System	19 Oct 2020 15:47:50
User entered 'None (0)'	System	19 Oct 2020 15:47:50

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:47:21', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c3ccf3db-eeef-4028-995a-ea08b188e0aa'	System	19 Oct 2020 15:47:50
User entered 'None (0)'	System	19 Oct 2020 15:47:50

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:47:36', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c3ccf3db-eeef-4028-995a-ea08b188e0aa'	System	19 Oct 2020 15:47:50
User entered 'No (N)'	System	19 Oct 2020 15:47:50

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T11:47:41', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c3ccf3db-eeef-4028-995a-ea08b188e0aa'	System	19 Oct 2020 15:47:50
User entered '19 Oct 2020 11:47'	System	19 Oct 2020 15:47:50

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Oct 2020 11:19'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Oct 2020 13:49'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:07:40', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9e32eb98-1b95-4646-b1a2-17822402347b'	System	19 Oct 2020 23:08:48
User entered 'None (0)'	System	19 Oct 2020 23:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:07:49', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9e32eb98-1b95-4646-b1a2-17822402347b'	System	19 Oct 2020 23:08:48
User entered 'None (0)'	System	19 Oct 2020 23:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:07:56', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9e32eb98-1b95-4646-b1a2-17822402347b'	System	19 Oct 2020 23:08:48
User entered 'None (0)'	System	19 Oct 2020 23:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:08:06', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9e32eb98-1b95-4646-b1a2-17822402347b'	System	19 Oct 2020 23:08:48
User entered 'None (0)'	System	19 Oct 2020 23:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:08:14', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9e32eb98-1b95-4646-b1a2-17822402347b'	System	19 Oct 2020 23:08:48
User entered 'None (0)'	System	19 Oct 2020 23:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:08:18', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9e32eb98-1b95-4646-b1a2-17822402347b'	System	19 Oct 2020 23:08:48
User entered 'None (0)'	System	19 Oct 2020 23:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:08:32', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9e32eb98-1b95-4646-b1a2-17822402347b'	System	19 Oct 2020 23:08:48
User entered 'No (N)'	System	19 Oct 2020 23:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-19T19:08:45', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9e32eb98-1b95-4646-b1a2-17822402347b'	System	19 Oct 2020 23:08:48
User entered '19 Oct 2020 19:08'	System	19 Oct 2020 23:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Oct 2020 14:44'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 2'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:00:14', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea731ba2-9573-4b6f-99dd-b411dbc3e975'	System	21 Oct 2020 03:01:03
User entered 'None (0)'	System	21 Oct 2020 03:01:03

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:00:19', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea731ba2-9573-4b6f-99dd-b411dbc3e975'	System	21 Oct 2020 03:01:03
User entered 'None (0)'	System	21 Oct 2020 03:01:03

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:00:24', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea731ba2-9573-4b6f-99dd-b411dbc3e975'	System	21 Oct 2020 03:01:03
User entered 'None (0)'	System	21 Oct 2020 03:01:03

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:00:28', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea731ba2-9573-4b6f-99dd-b411dbc3e975'	System	21 Oct 2020 03:01:03
User entered 'None (0)'	System	21 Oct 2020 03:01:03

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:00:33', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea731ba2-9573-4b6f-99dd-b411dbc3e975'	System	21 Oct 2020 03:01:03
User entered 'None (0)'	System	21 Oct 2020 03:01:03

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:00:37', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea731ba2-9573-4b6f-99dd-b411dbc3e975'	System	21 Oct 2020 03:01:03
User entered 'None (0)'	System	21 Oct 2020 03:01:03

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:00:46', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea731ba2-9573-4b6f-99dd-b411dbc3e975'	System	21 Oct 2020 03:01:03
User entered 'No (N)'	System	21 Oct 2020 03:01:03

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-20T23:01:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea731ba2-9573-4b6f-99dd-b411dbc3e975'	System	21 Oct 2020 03:01:03
User entered '20 Oct 2020 23:01'	System	21 Oct 2020 03:01:03

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 3'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:23:48', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '52a12f35-0f15-4788-8d0b-707e138e5111'	System	21 Oct 2020 23:24:40
User entered 'None (0)'	System	21 Oct 2020 23:24:40

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:23:57', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '52a12f35-0f15-4788-8d0b-707e138e5111'	System	21 Oct 2020 23:24:40
User entered 'None (0)'	System	21 Oct 2020 23:24:40

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:24:02', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '52a12f35-0f15-4788-8d0b-707e138e5111'	System	21 Oct 2020 23:24:40
User entered 'None (0)'	System	21 Oct 2020 23:24:40

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:24:09', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '52a12f35-0f15-4788-8d0b-707e138e5111'	System	21 Oct 2020 23:24:40
User entered 'None (0)'	System	21 Oct 2020 23:24:40

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:24:16', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '52a12f35-0f15-4788-8d0b-707e138e5111'	System	21 Oct 2020 23:24:40
User entered 'None (0)'	System	21 Oct 2020 23:24:40

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:24:20', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '52a12f35-0f15-4788-8d0b-707e138e5111'	System	21 Oct 2020 23:24:40
User entered 'None (0)'	System	21 Oct 2020 23:24:40

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:24:28', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '52a12f35-0f15-4788-8d0b-707e138e5111'	System	21 Oct 2020 23:24:40
User entered 'No (N)'	System	21 Oct 2020 23:24:40

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-21T19:24:37', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '52a12f35-0f15-4788-8d0b-707e138e5111'	System	21 Oct 2020 23:24:40
User entered '21 Oct 2020 19:24'	System	21 Oct 2020 23:24:40

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 4'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:12', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b25c16f9-faeb-492d-af9a-d439e4ccf4d5'	System	23 Oct 2020 00:53:47
User entered 'None (0)'	System	23 Oct 2020 00:53:47

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:16', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b25c16f9-faeb-492d-af9a-d439e4ccf4d5'	System	23 Oct 2020 00:53:47
User entered 'None (0)'	System	23 Oct 2020 00:53:47

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:19', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b25c16f9-faeb-492d-af9a-d439e4ccf4d5'	System	23 Oct 2020 00:53:47
User entered 'None (0)'	System	23 Oct 2020 00:53:47

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:23', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b25c16f9-faeb-492d-af9a-d439e4ccf4d5'	System	23 Oct 2020 00:53:47
User entered 'None (0)'	System	23 Oct 2020 00:53:47

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:26', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b25c16f9-faeb-492d-af9a-d439e4ccf4d5'	System	23 Oct 2020 00:53:47
User entered 'None (0)'	System	23 Oct 2020 00:53:47

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:29', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b25c16f9-faeb-492d-af9a-d439e4ccf4d5'	System	23 Oct 2020 00:53:47
User entered 'None (0)'	System	23 Oct 2020 00:53:47

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:36', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b25c16f9-faeb-492d-af9a-d439e4ccf4d5'	System	23 Oct 2020 00:53:47
User entered 'No (N)'	System	23 Oct 2020 00:53:47

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-22T20:53:43', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b25c16f9-faeb-492d-af9a-d439e4ccf4d5'	System	23 Oct 2020 00:53:47
User entered '22 Oct 2020 20:53'	System	23 Oct 2020 00:53:47

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 5'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:44:04', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c1473afd-39c3-4eb4-93d1-6238bba7cdba'	System	23 Oct 2020 23:44:41
User entered 'None (0)'	System	23 Oct 2020 23:44:41

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:44:08', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c1473afd-39c3-4eb4-93d1-6238bba7cdba'	System	23 Oct 2020 23:44:41
User entered 'None (0)'	System	23 Oct 2020 23:44:41

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:44:14', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c1473afd-39c3-4eb4-93d1-6238bba7cdba'	System	23 Oct 2020 23:44:41
User entered 'None (0)'	System	23 Oct 2020 23:44:41

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:44:18', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c1473afd-39c3-4eb4-93d1-6238bba7cdba'	System	23 Oct 2020 23:44:41
User entered 'None (0)'	System	23 Oct 2020 23:44:41

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:44:21', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c1473afd-39c3-4eb4-93d1-6238bba7cdba'	System	23 Oct 2020 23:44:41
User entered 'None (0)'	System	23 Oct 2020 23:44:41

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:44:24', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c1473afd-39c3-4eb4-93d1-6238bba7cdba'	System	23 Oct 2020 23:44:41
User entered 'None (0)'	System	23 Oct 2020 23:44:41

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:44:32', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c1473afd-39c3-4eb4-93d1-6238bba7cdba'	System	23 Oct 2020 23:44:41
User entered 'No (N)'	System	23 Oct 2020 23:44:41

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-23T19:44:38', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c1473afd-39c3-4eb4-93d1-6238bba7cdba'	System	23 Oct 2020 23:44:41
User entered '23 Oct 2020 19:44'	System	23 Oct 2020 23:44:41

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 6'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:44', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b3f2d46b-1637-49e5-8bdc-42d6238056a9'	System	24 Oct 2020 23:32:13
User entered 'None (0)'	System	24 Oct 2020 23:32:13

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:47', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b3f2d46b-1637-49e5-8bdc-42d6238056a9'	System	24 Oct 2020 23:32:13
User entered 'None (0)'	System	24 Oct 2020 23:32:13

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:50', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b3f2d46b-1637-49e5-8bdc-42d6238056a9'	System	24 Oct 2020 23:32:13
User entered 'None (0)'	System	24 Oct 2020 23:32:13

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:55', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b3f2d46b-1637-49e5-8bdc-42d6238056a9'	System	24 Oct 2020 23:32:13
User entered 'None (0)'	System	24 Oct 2020 23:32:13

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:31:57', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b3f2d46b-1637-49e5-8bdc-42d6238056a9'	System	24 Oct 2020 23:32:13
User entered 'None (0)'	System	24 Oct 2020 23:32:13

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:32:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b3f2d46b-1637-49e5-8bdc-42d6238056a9'	System	24 Oct 2020 23:32:13
User entered 'None (0)'	System	24 Oct 2020 23:32:13

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:32:04', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b3f2d46b-1637-49e5-8bdc-42d6238056a9'	System	24 Oct 2020 23:32:13
User entered 'No (N)'	System	24 Oct 2020 23:32:13

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-24T19:32:11', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'b3f2d46b-1637-49e5-8bdc-42d6238056a9'	System	24 Oct 2020 23:32:13
User entered '24 Oct 2020 19:32'	System	24 Oct 2020 23:32:13

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	19 Oct 2020 15:08:48
User entered 'Day 7'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:39', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '00c00e59-a468-4c64-98ce-338b5d05cf63'	System	25 Oct 2020 23:45:18
User entered 'None (0)'	System	25 Oct 2020 23:45:18

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:45', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '00c00e59-a468-4c64-98ce-338b5d05cf63'	System	25 Oct 2020 23:45:18
User entered 'None (0)'	System	25 Oct 2020 23:45:18

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:49', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '00c00e59-a468-4c64-98ce-338b5d05cf63'	System	25 Oct 2020 23:45:18
User entered 'None (0)'	System	25 Oct 2020 23:45:18

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:44:53', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '00c00e59-a468-4c64-98ce-338b5d05cf63'	System	25 Oct 2020 23:45:18
User entered 'None (0)'	System	25 Oct 2020 23:45:18

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:45:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '00c00e59-a468-4c64-98ce-338b5d05cf63'	System	25 Oct 2020 23:45:18
User entered 'None (0)'	System	25 Oct 2020 23:45:18

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:45:03', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '00c00e59-a468-4c64-98ce-338b5d05cf63'	System	25 Oct 2020 23:45:18
User entered 'None (0)'	System	25 Oct 2020 23:45:18

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:45:08', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '00c00e59-a468-4c64-98ce-338b5d05cf63'	System	25 Oct 2020 23:45:18
User entered 'No (N)'	System	25 Oct 2020 23:45:18

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-10-25T19:45:17', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '00c00e59-a468-4c64-98ce-338b5d05cf63'	System	25 Oct 2020 23:45:18
User entered '25 Oct 2020 19:45'	System	25 Oct 2020 23:45:18

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 15:08:48

US3482302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 15:08:48

US3482302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Oct 2020 19:35:30

US3482302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '26 Oct 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Oct 2020 19:35:30

US3482302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4)	26 Oct 2020 19:35:30

US3482302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	26 Oct 2020 19:35:30
	(b) (4)	

US3482302

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Oct 2020 19:35:42

US3482302

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'I'	System	26 Oct 2020 19:35:42

US3482302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	02 Nov 2020 21:24:42

US3482302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '2 Nov 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	02 Nov 2020 21:24:42

US3482302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4)	02 Nov 2020 21:24:42

US3482302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	02 Nov 2020 21:24:42

US3482302

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	02 Nov 2020 21:24:48

US3482302

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:05:37
User entered 'I'	System	02 Nov 2020 21:24:48

US3482302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:03
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	13 Nov 2020 17:43:58

US3482302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:03
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '12 Nov 2020'	(b) (4) Sarah Bechnak (b) (4)	13 Nov 2020 17:43:58
	(b) (4)	

US3482302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:03
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4)	13 Nov 2020 17:43:58

US3482302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:03
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	13 Nov 2020 17:43:58

US3482302

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:03
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	13 Nov 2020 17:44:02

US3482302

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:03
User entered 'I'	System	13 Nov 2020 17:44:02

US3482302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:17

US3482302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:17

US3482302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:17

US3482302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'VISIT2'	System	16 Nov 2020 14:29:17

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '09:05'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered '16 Nov 2020 09:05'	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '64'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'bpm'	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'breaths/min'	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '136'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'mmHg'	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '72'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'mmHg'	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	16 Nov 2020 16:14:49
User entered '16 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 16:14:49
User opened query 'Data is required. Please provide.' (Site from System).		
	System	16 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 16:14:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Nov 2020 16:14:49
User entered '10:35' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 16:14:49
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered '16 Nov 2020 10:35'	System	16 Nov 2020 16:14:49
User entered empty.	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 16:14:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Nov 2020 16:14:49
User entered '98.1' F reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 16:14:49
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 16:14:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Nov 2020 16:14:56
User entered 'Oral (Oral)' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 16:14:56
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 16:14:49
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	16 Nov 2020 16:14:49
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Nov 2020 16:14:49
User entered '63' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 16:14:49
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Nov 2020 16:12:42
User entered '6'	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'bpm'	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 16:14:49
Query 'Data is required. Please provide.' answered by System	System	16 Nov 2020 16:14:49
data change (Site from System).		16 Nov 2020 16:14:49
User entered '16' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 16:14:49
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'breaths/min'	System	16 Nov 2020 16:14:49
User entered empty.	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 16:14:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Nov 2020 16:14:49
User entered '137' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 16:14:49
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'mmHg'	System	16 Nov 2020 16:14:49
User entered empty.	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 16:14:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Nov 2020 16:14:49
User entered '73' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 16:14:49
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'mmHg'	System	16 Nov 2020 16:14:49
User entered empty.	System	16 Nov 2020 16:12:42

US3482302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:27

US3482302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:27

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'MRNA-1273 OR PLACEBO'	System	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '10:03'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered '16 Nov 2020 10:03'	System	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'ONCE'	System	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'INTRAMUSCULAR'	System	16 Nov 2020 15:07:32

US3482302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:53:00

US3482302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:53:00

US3482302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '09:35'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:53:00

US3482302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered '16 Nov 2020 09:35'	System	16 Nov 2020 14:53:00

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:44:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:53:19

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Nov 2020 14:53:19

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:53:19

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '09:44'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:53:19

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered '16 Nov 2020 09:44'	System	16 Nov 2020 14:53:19

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Nov 2020 14:53:19

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:53:19

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:53:19

US3482302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered empty.	System	16 Nov 2020 14:53:19

US3482302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:15:01

US3482302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'I'	System	16 Nov 2020 16:15:01

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:40:01', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7aaf1349-a369-41d5-aaba-2822bfdd0bb7'	System	16 Nov 2020 15:40:22
User entered 'Yes (Y)'	System	16 Nov 2020 15:40:22

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:40:09', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7aaf1349-a369-41d5-aaba-2822bfdd0bb7'	System	16 Nov 2020 15:40:22
User entered '98.1'	System	16 Nov 2020 15:40:22

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:40:14', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7aaf1349-a369-41d5-aaba-2822bfdd0bb7'	System	16 Nov 2020 15:40:22
User entered 'No (N)'	System	16 Nov 2020 15:40:22

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:40:19', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7aaf1349-a369-41d5-aaba-2822bfdd0bb7'	System	16 Nov 2020 15:40:22
User entered '16 Nov 2020 10:40'	System	16 Nov 2020 15:40:22

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '16 Nov 2020 10:23'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '16 Nov 2020 12:53'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T09:47:43', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1de6cee4-22c9-4617-b5ca-d8a1c9d8e939'	System	17 Nov 2020 14:48:06
User entered 'Yes (Y)'	System	17 Nov 2020 14:48:06

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T09:47:54', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1de6cee4-22c9-4617-b5ca-d8a1c9d8e939'	System	17 Nov 2020 14:48:06
User entered '97.7'	System	17 Nov 2020 14:48:06

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T09:47:58', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1de6cee4-22c9-4617-b5ca-d8a1c9d8e939'	System	17 Nov 2020 14:48:06
User entered 'No (N)'	System	17 Nov 2020 14:48:06

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T09:48:03', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1de6cee4-22c9-4617-b5ca-d8a1c9d8e939'	System	17 Nov 2020 14:48:06
User entered '17 Nov 2020 09:48'	System	17 Nov 2020 14:48:06

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '16 Nov 2020 13:48'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 2'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:32:27', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '051442d5-16b6-47c7-8886-9dfa7a347e26'	System	18 Nov 2020 02:32:45
User entered 'Yes (Y)'	System	18 Nov 2020 02:32:45

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:32:34', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '051442d5-16b6-47c7-8886-9dfa7a347e26'	System	18 Nov 2020 02:32:45
User entered '98.3'	System	18 Nov 2020 02:32:45

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:32:37', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '051442d5-16b6-47c7-8886-9dfa7a347e26'	System	18 Nov 2020 02:32:45
User entered 'No (N)'	System	18 Nov 2020 02:32:45

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:32:42', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '051442d5-16b6-47c7-8886-9dfa7a347e26'	System	18 Nov 2020 02:32:45
User entered '17 Nov 2020 21:32'	System	18 Nov 2020 02:32:45

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 3'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:53:17', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5af3d11d-92ea-4307-b0dd-0dac4067a37a'	System	19 Nov 2020 03:53:35
User entered 'Yes (Y)'	System	19 Nov 2020 03:53:35

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:53:24', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5af3d11d-92ea-4307-b0dd-0dac4067a37a'	System	19 Nov 2020 03:53:35
User entered '97.9'	System	19 Nov 2020 03:53:35

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:53:28', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5af3d11d-92ea-4307-b0dd-0dac4067a37a'	System	19 Nov 2020 03:53:35
User entered 'No (N)'	System	19 Nov 2020 03:53:35

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:53:32', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5af3d11d-92ea-4307-b0dd-0dac4067a37a'	System	19 Nov 2020 03:53:35
User entered '18 Nov 2020 22:53'	System	19 Nov 2020 03:53:35

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 4'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:00:57', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd2e5a728-9528-4061-a1bb-fefa8c108db0'	System	20 Nov 2020 03:01:15
User entered 'Yes (Y)'	System	20 Nov 2020 03:01:15

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:05', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd2e5a728-9528-4061-a1bb-fefa8c108db0'	System	20 Nov 2020 03:01:15
User entered '98.2'	System	20 Nov 2020 03:01:15

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:09', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd2e5a728-9528-4061-a1bb-fefa8c108db0'	System	20 Nov 2020 03:01:15
User entered 'No (N)'	System	20 Nov 2020 03:01:15

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:12', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd2e5a728-9528-4061-a1bb-fefa8c108db0'	System	20 Nov 2020 03:01:15
User entered '19 Nov 2020 22:01'	System	20 Nov 2020 03:01:15

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 5'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:06:08', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '588c268b-1c4f-476c-95e7-d2c2d6bf5c88'	System	21 Nov 2020 03:17:45
User entered 'Yes (Y)'	System	21 Nov 2020 03:17:45

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:06:15', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '588c268b-1c4f-476c-95e7-d2c2d6bf5c88'	System	21 Nov 2020 03:17:45
User entered '98.1'	System	21 Nov 2020 03:17:45

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:06:24', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '588c268b-1c4f-476c-95e7-d2c2d6bf5c88'	System	21 Nov 2020 03:17:45
User entered 'No (N)'	System	21 Nov 2020 03:17:45

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:07:14', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '588c268b-1c4f-476c-95e7-d2c2d6bf5c88'	System	21 Nov 2020 03:17:45
User entered '20 Nov 2020 22:07'	System	21 Nov 2020 03:17:45

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 6'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:34:39', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8deb2621-1f57-4474-bed5-33091534c272'	System	22 Nov 2020 02:34:57
User entered 'Yes (Y)'	System	22 Nov 2020 02:34:57

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:34:44', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8deb2621-1f57-4474-bed5-33091534c272'	System	22 Nov 2020 02:34:57
User entered '98.1'	System	22 Nov 2020 02:34:57

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:34:48', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8deb2621-1f57-4474-bed5-33091534c272'	System	22 Nov 2020 02:34:57
User entered 'No (N)'	System	22 Nov 2020 02:34:57

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:34:53', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8deb2621-1f57-4474-bed5-33091534c272'	System	22 Nov 2020 02:34:57
User entered '21 Nov 2020 21:34'	System	22 Nov 2020 02:34:57

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 7'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:45:31', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'a177730a-aa5f-4637-a009-0143de6a3bec'	System	23 Nov 2020 02:46:01
User entered 'Yes (Y)'	System	23 Nov 2020 02:46:01

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:45:49', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'a177730a-aa5f-4637-a009-0143de6a3bec'	System	23 Nov 2020 02:46:01
User entered '98.0'	System	23 Nov 2020 02:46:01

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:45:55', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'a177730a-aa5f-4637-a009-0143de6a3bec'	System	23 Nov 2020 02:46:01
User entered 'No (N)'	System	23 Nov 2020 02:46:01

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:45:58', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'a177730a-aa5f-4637-a009-0143de6a3bec'	System	23 Nov 2020 02:46:01
User entered '22 Nov 2020 21:45'	System	23 Nov 2020 02:46:01

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:40:33', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1fd8fd15-57d8-48b0-aff9-17dd9558a80d'	System	16 Nov 2020 15:41:12
User entered 'None (1)'	System	16 Nov 2020 15:41:12

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:40:40', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1fd8fd15-57d8-48b0-aff9-17dd9558a80d'	System	16 Nov 2020 15:41:12
User entered 'No (N)'	System	16 Nov 2020 15:41:12

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:40:46', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1fd8fd15-57d8-48b0-aff9-17dd9558a80d'	System	16 Nov 2020 15:41:12
User entered 'No (N)'	System	16 Nov 2020 15:41:12

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:40:54', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1fd8fd15-57d8-48b0-aff9-17dd9558a80d'	System	16 Nov 2020 15:41:12
User entered 'None (1)'	System	16 Nov 2020 15:41:12

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:41:07', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1fd8fd15-57d8-48b0-aff9-17dd9558a80d'	System	16 Nov 2020 15:41:12
User entered '16 Nov 2020 10:41'	System	16 Nov 2020 15:41:12

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '16 Nov 2020 10:23'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '16 Nov 2020 12:53'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T09:48:20', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1b740733-0da0-4dfe-b3f1-7fbbab924827'	System	17 Nov 2020 14:49:33
User entered 'None (1)'	System	17 Nov 2020 14:49:33

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T09:48:36', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1b740733-0da0-4dfe-b3f1-7fbbab924827'	System	17 Nov 2020 14:49:33
User entered 'No (N)'	System	17 Nov 2020 14:49:33

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T09:48:41', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1b740733-0da0-4dfe-b3f1-7fbbab924827'	System	17 Nov 2020 14:49:33
User entered 'No (N)'	System	17 Nov 2020 14:49:33

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T09:49:17', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1b740733-0da0-4dfe-b3f1-7fbbab924827'	System	17 Nov 2020 14:49:33
User entered 'None (1)'	System	17 Nov 2020 14:49:33

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T09:49:27', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '1b740733-0da0-4dfe-b3f1-7fbbab924827'	System	17 Nov 2020 14:49:33
User entered '17 Nov 2020 09:49'	System	17 Nov 2020 14:49:33

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '16 Nov 2020 13:48'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 2'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:32:51', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'aed87a07-2064-441f-b344-dbd7264545da'	System	18 Nov 2020 02:33:17
User entered 'None (1)'	System	18 Nov 2020 02:33:17

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:32:55', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'aed87a07-2064-441f-b344-dbd7264545da'	System	18 Nov 2020 02:33:17
User entered 'No (N)'	System	18 Nov 2020 02:33:17

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:33:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'aed87a07-2064-441f-b344-dbd7264545da'	System	18 Nov 2020 02:33:17
User entered 'No (N)'	System	18 Nov 2020 02:33:17

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:33:06', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'aed87a07-2064-441f-b344-dbd7264545da'	System	18 Nov 2020 02:33:17
User entered 'None (1)'	System	18 Nov 2020 02:33:17

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:33:11', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'aed87a07-2064-441f-b344-dbd7264545da'	System	18 Nov 2020 02:33:17
User entered '17 Nov 2020 21:33'	System	18 Nov 2020 02:33:17

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 3'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:53:39', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9d661e48-143a-48c6-8d8e-b79e6e27794e'	System	19 Nov 2020 03:54:09
User entered 'None (1)'	System	19 Nov 2020 03:54:09

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:53:47', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9d661e48-143a-48c6-8d8e-b79e6e27794e'	System	19 Nov 2020 03:54:09
User entered 'No (N)'	System	19 Nov 2020 03:54:09

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:53:50', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9d661e48-143a-48c6-8d8e-b79e6e27794e'	System	19 Nov 2020 03:54:09
User entered 'No (N)'	System	19 Nov 2020 03:54:09

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:53:56', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9d661e48-143a-48c6-8d8e-b79e6e27794e'	System	19 Nov 2020 03:54:09
User entered 'None (1)'	System	19 Nov 2020 03:54:09

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:54:06', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9d661e48-143a-48c6-8d8e-b79e6e27794e'	System	19 Nov 2020 03:54:09
User entered '18 Nov 2020 22:54'	System	19 Nov 2020 03:54:09

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 4'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:30', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '0c220504-369e-4348-86aa-e71550d0e718'	System	20 Nov 2020 03:01:50
User entered 'None (1)'	System	20 Nov 2020 03:01:50

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:34', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '0c220504-369e-4348-86aa-e71550d0e718'	System	20 Nov 2020 03:01:50
User entered 'No (N)'	System	20 Nov 2020 03:01:50

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:38', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '0c220504-369e-4348-86aa-e71550d0e718'	System	20 Nov 2020 03:01:50
User entered 'No (N)'	System	20 Nov 2020 03:01:50

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:43', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '0c220504-369e-4348-86aa-e71550d0e718'	System	20 Nov 2020 03:01:50
User entered 'None (1)'	System	20 Nov 2020 03:01:50

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:46', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '0c220504-369e-4348-86aa-e71550d0e718'	System	20 Nov 2020 03:01:50
User entered '19 Nov 2020 22:01'	System	20 Nov 2020 03:01:50

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 5'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:07:31', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7e19c7a6-adb3-4930-9476-8ca2fd85a3ad'	System	21 Nov 2020 03:17:53
User entered 'None (1)'	System	21 Nov 2020 03:17:53

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:07:35', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7e19c7a6-adb3-4930-9476-8ca2fd85a3ad'	System	21 Nov 2020 03:17:53
User entered 'No (N)'	System	21 Nov 2020 03:17:53

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:07:39', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7e19c7a6-adb3-4930-9476-8ca2fd85a3ad'	System	21 Nov 2020 03:17:53
User entered 'No (N)'	System	21 Nov 2020 03:17:53

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:07:49', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7e19c7a6-adb3-4930-9476-8ca2fd85a3ad'	System	21 Nov 2020 03:17:53
User entered 'None (1)'	System	21 Nov 2020 03:17:53

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:08:03', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '7e19c7a6-adb3-4930-9476-8ca2fd85a3ad'	System	21 Nov 2020 03:17:53
User entered '20 Nov 2020 22:08'	System	21 Nov 2020 03:17:53

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 6'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:04', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '11811100-6019-4076-af96-9b53473f367e'	System	22 Nov 2020 02:35:27
User entered 'None (1)'	System	22 Nov 2020 02:35:27

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:08', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '11811100-6019-4076-af96-9b53473f367e'	System	22 Nov 2020 02:35:27
User entered 'No (N)'	System	22 Nov 2020 02:35:27

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:12', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '11811100-6019-4076-af96-9b53473f367e'	System	22 Nov 2020 02:35:27
User entered 'No (N)'	System	22 Nov 2020 02:35:27

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:16', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '11811100-6019-4076-af96-9b53473f367e'	System	22 Nov 2020 02:35:27
User entered 'None (1)'	System	22 Nov 2020 02:35:27

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:22', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '11811100-6019-4076-af96-9b53473f367e'	System	22 Nov 2020 02:35:27
User entered '21 Nov 2020 21:35'	System	22 Nov 2020 02:35:27

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 7'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:46:08', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '635ffa36-5f8e-40a7-b6bc-01fcb891cc54'	System	23 Nov 2020 02:46:35
User entered 'None (1)'	System	23 Nov 2020 02:46:35

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:46:13', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '635ffa36-5f8e-40a7-b6bc-01fcb891cc54'	System	23 Nov 2020 02:46:35
User entered 'No (N)'	System	23 Nov 2020 02:46:35

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:46:18', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '635ffa36-5f8e-40a7-b6bc-01fcb891cc54'	System	23 Nov 2020 02:46:35
User entered 'No (N)'	System	23 Nov 2020 02:46:35

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:46:23', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '635ffa36-5f8e-40a7-b6bc-01fcb891cc54'	System	23 Nov 2020 02:46:35
User entered 'None (1)'	System	23 Nov 2020 02:46:35

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:46:30', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '635ffa36-5f8e-40a7-b6bc-01fcb891cc54'	System	23 Nov 2020 02:46:35
User entered '22 Nov 2020 21:46'	System	23 Nov 2020 02:46:35

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:41:29', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '643f26bb-cdbe-454b-935c-94a81e52e933'	System	16 Nov 2020 15:42:17
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		16 Nov 2020 15:42:17

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:41:41', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '643f26bb-cdbe-454b-935c-94a81e52e933'	System	16 Nov 2020 15:42:17
User entered 'None (0)'	System	16 Nov 2020 15:42:17

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:41:45', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '643f26bb-cdbe-454b-935c-94a81e52e933'	System	16 Nov 2020 15:42:17
User entered 'None (0)'	System	16 Nov 2020 15:42:17

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:41:48', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '643f26bb-cdbe-454b-935c-94a81e52e933'	System	16 Nov 2020 15:42:17
User entered 'None (0)'	System	16 Nov 2020 15:42:17

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:41:50', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '643f26bb-cdbe-454b-935c-94a81e52e933'	System	16 Nov 2020 15:42:17
User entered 'None (0)'	System	16 Nov 2020 15:42:17

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:41:54', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '643f26bb-cdbe-454b-935c-94a81e52e933'	System	16 Nov 2020 15:42:17
User entered 'None (0)'	System	16 Nov 2020 15:42:17

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:42:06', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '643f26bb-cdbe-454b-935c-94a81e52e933'	System	16 Nov 2020 15:42:17
User entered 'No (N)'	System	16 Nov 2020 15:42:17

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-16T10:42:11', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '643f26bb-cdbe-454b-935c-94a81e52e933'	System	16 Nov 2020 15:42:17
User entered '16 Nov 2020 10:42'	System	16 Nov 2020 15:42:17

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '16 Nov 2020 10:23'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '16 Nov 2020 12:53'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '16 Nov 2020 13:48'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 2'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:35:32', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '01610f61-c294-450d-a7ee-4471872bfb5f'	System	18 Nov 2020 02:36:06
User entered 'None (0)'	System	18 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:35:36', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '01610f61-c294-450d-a7ee-4471872bfb5f'	System	18 Nov 2020 02:36:06
User entered 'None (0)'	System	18 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:35:38', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '01610f61-c294-450d-a7ee-4471872bfb5f'	System	18 Nov 2020 02:36:06
User entered 'None (0)'	System	18 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:35:44', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '01610f61-c294-450d-a7ee-4471872bfb5f'	System	18 Nov 2020 02:36:06
User entered 'None (0)'	System	18 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:35:47', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '01610f61-c294-450d-a7ee-4471872bfb5f'	System	18 Nov 2020 02:36:06
User entered 'None (0)'	System	18 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:35:52', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '01610f61-c294-450d-a7ee-4471872bfb5f'	System	18 Nov 2020 02:36:06
User entered 'None (0)'	System	18 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:35:59', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '01610f61-c294-450d-a7ee-4471872bfb5f'	System	18 Nov 2020 02:36:06
User entered 'No (N)'	System	18 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-17T21:36:03', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '01610f61-c294-450d-a7ee-4471872bfb5f'	System	18 Nov 2020 02:36:06
User entered '17 Nov 2020 21:36'	System	18 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 3'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:54:12', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'e2a6e9c1-d106-4c14-afeb-ca5e4446afd6'	System	19 Nov 2020 03:54:55
User entered 'None (0)'	System	19 Nov 2020 03:54:55

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:54:25', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'e2a6e9c1-d106-4c14-afeb-ca5e4446afd6'	System	19 Nov 2020 03:54:55
User entered 'None (0)'	System	19 Nov 2020 03:54:55

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:54:29', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'e2a6e9c1-d106-4c14-afeb-ca5e4446afd6'	System	19 Nov 2020 03:54:55
User entered 'None (0)'	System	19 Nov 2020 03:54:55

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:54:34', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'e2a6e9c1-d106-4c14-afeb-ca5e4446afd6'	System	19 Nov 2020 03:54:55
User entered 'None (0)'	System	19 Nov 2020 03:54:55

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:54:38', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'e2a6e9c1-d106-4c14-afeb-ca5e4446afd6'	System	19 Nov 2020 03:54:55
User entered 'None (0)'	System	19 Nov 2020 03:54:55

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:54:41', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'e2a6e9c1-d106-4c14-afeb-ca5e4446afd6'	System	19 Nov 2020 03:54:55
User entered 'None (0)'	System	19 Nov 2020 03:54:55

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:54:47', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'e2a6e9c1-d106-4c14-afeb-ca5e4446afd6'	System	19 Nov 2020 03:54:55
User entered 'No (N)'	System	19 Nov 2020 03:54:55

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-18T22:54:52', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'e2a6e9c1-d106-4c14-afeb-ca5e4446afd6'	System	19 Nov 2020 03:54:55
User entered '18 Nov 2020 22:54'	System	19 Nov 2020 03:54:55

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 4'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:52', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '141d1b54-28a9-4ff5-9cbd-68e5ed2ddedf'	System	20 Nov 2020 03:02:15
User entered 'None (0)'	System	20 Nov 2020 03:02:15

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:55', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '141d1b54-28a9-4ff5-9cbd-68e5ed2ddedf'	System	20 Nov 2020 03:02:15
User entered 'None (0)'	System	20 Nov 2020 03:02:15

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:01:58', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '141d1b54-28a9-4ff5-9cbd-68e5ed2ddedf'	System	20 Nov 2020 03:02:15
User entered 'None (0)'	System	20 Nov 2020 03:02:15

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:02:01', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '141d1b54-28a9-4ff5-9cbd-68e5ed2ddedf'	System	20 Nov 2020 03:02:15
User entered 'None (0)'	System	20 Nov 2020 03:02:15

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:02:03', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '141d1b54-28a9-4ff5-9cbd-68e5ed2ddedf'	System	20 Nov 2020 03:02:15
User entered 'None (0)'	System	20 Nov 2020 03:02:15

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:02:06', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '141d1b54-28a9-4ff5-9cbd-68e5ed2ddedf'	System	20 Nov 2020 03:02:15
User entered 'None (0)'	System	20 Nov 2020 03:02:15

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:02:08', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '141d1b54-28a9-4ff5-9cbd-68e5ed2ddedf'	System	20 Nov 2020 03:02:15
User entered 'No (N)'	System	20 Nov 2020 03:02:15

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-19T22:02:13', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '141d1b54-28a9-4ff5-9cbd-68e5ed2ddedf'	System	20 Nov 2020 03:02:15
User entered '19 Nov 2020 22:02'	System	20 Nov 2020 03:02:15

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 5'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:08:30', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea69d6c8-fcf6-488a-b31e-c4ff431560fc'	System	21 Nov 2020 03:18:14
User entered 'None (0)'	System	21 Nov 2020 03:18:14

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:08:34', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea69d6c8-fcf6-488a-b31e-c4ff431560fc'	System	21 Nov 2020 03:18:14
User entered 'None (0)'	System	21 Nov 2020 03:18:14

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:08:39', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea69d6c8-fcf6-488a-b31e-c4ff431560fc'	System	21 Nov 2020 03:18:14
User entered 'None (0)'	System	21 Nov 2020 03:18:14

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:08:44', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea69d6c8-fcf6-488a-b31e-c4ff431560fc'	System	21 Nov 2020 03:18:14
User entered 'None (0)'	System	21 Nov 2020 03:18:14

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:08:49', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea69d6c8-fcf6-488a-b31e-c4ff431560fc'	System	21 Nov 2020 03:18:14
User entered 'None (0)'	System	21 Nov 2020 03:18:14

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:08:52', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea69d6c8-fcf6-488a-b31e-c4ff431560fc'	System	21 Nov 2020 03:18:14
User entered 'None (0)'	System	21 Nov 2020 03:18:14

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:09:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea69d6c8-fcf6-488a-b31e-c4ff431560fc'	System	21 Nov 2020 03:18:14
User entered 'No (N)'	System	21 Nov 2020 03:18:14

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-20T22:09:06', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'ea69d6c8-fcf6-488a-b31e-c4ff431560fc'	System	21 Nov 2020 03:18:14
User entered '20 Nov 2020 22:09'	System	21 Nov 2020 03:18:14

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 6'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:30', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18f1bcd7-7265-4f2d-81b5-d87ce4211c00'	System	22 Nov 2020 02:36:06
User entered 'None (0)'	System	22 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:34', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18f1bcd7-7265-4f2d-81b5-d87ce4211c00'	System	22 Nov 2020 02:36:06
User entered 'None (0)'	System	22 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:37', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18f1bcd7-7265-4f2d-81b5-d87ce4211c00'	System	22 Nov 2020 02:36:06
User entered 'None (0)'	System	22 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:42', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18f1bcd7-7265-4f2d-81b5-d87ce4211c00'	System	22 Nov 2020 02:36:06
User entered 'None (0)'	System	22 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:46', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18f1bcd7-7265-4f2d-81b5-d87ce4211c00'	System	22 Nov 2020 02:36:06
User entered 'None (0)'	System	22 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:49', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18f1bcd7-7265-4f2d-81b5-d87ce4211c00'	System	22 Nov 2020 02:36:06
User entered 'None (0)'	System	22 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:35:54', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18f1bcd7-7265-4f2d-81b5-d87ce4211c00'	System	22 Nov 2020 02:36:06
User entered 'No (N)'	System	22 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-21T21:36:01', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18f1bcd7-7265-4f2d-81b5-d87ce4211c00'	System	22 Nov 2020 02:36:06
User entered '21 Nov 2020 21:36'	System	22 Nov 2020 02:36:06

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
Data entry locked.	System	16 Nov 2020 15:07:32
User entered 'Day 7'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:46:40', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '2724ff4b-aea9-4d34-8788-16843030d2ee'	System	23 Nov 2020 02:47:31
User entered 'None (0)'	System	23 Nov 2020 02:47:31

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:46:45', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '2724ff4b-aea9-4d34-8788-16843030d2ee'	System	23 Nov 2020 02:47:31
User entered 'None (0)'	System	23 Nov 2020 02:47:31

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:46:51', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '2724ff4b-aea9-4d34-8788-16843030d2ee'	System	23 Nov 2020 02:47:31
User entered 'None (0)'	System	23 Nov 2020 02:47:31

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:46:56', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '2724ff4b-aea9-4d34-8788-16843030d2ee'	System	23 Nov 2020 02:47:31
User entered 'None (0)'	System	23 Nov 2020 02:47:31

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:47:04', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '2724ff4b-aea9-4d34-8788-16843030d2ee'	System	23 Nov 2020 02:47:31
User entered 'None (0)'	System	23 Nov 2020 02:47:31

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:47:07', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '2724ff4b-aea9-4d34-8788-16843030d2ee'	System	23 Nov 2020 02:47:31
User entered 'None (0)'	System	23 Nov 2020 02:47:31

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

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)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:47:19', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '2724ff4b-aea9-4d34-8788-16843030d2ee'	System	23 Nov 2020 02:47:31
User entered 'No (N)'	System	23 Nov 2020 02:47:31

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-11-22T21:47:28', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '2724ff4b-aea9-4d34-8788-16843030d2ee'	System	23 Nov 2020 02:47:31
User entered '22 Nov 2020 21:47'	System	23 Nov 2020 02:47:31

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 15:07:32

US3482302

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:51:32
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 15:07:32

US3482302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 13:31:02

US3482302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '24 Nov 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 13:31:02

US3482302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 13:31:02

US3482302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 13:31:02

US3482302

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 13:31:06

US3482302

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'I'	System	01 Dec 2020 13:31:06

US3482302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 19:56:42

US3482302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '1 Dec 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 19:56:42

US3482302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 19:56:42

US3482302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 19:56:42

US3482302

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 19:56:46

US3482302

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'I'	System	01 Dec 2020 19:56:46

US3482302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 15:49:05

US3482302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered '8 Dec 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 15:49:05

US3482302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 15:49:05

US3482302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 15:49:05

US3482302

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:33
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 15:49:11

US3482302

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'I'	System	08 Dec 2020 15:49:11

US3482302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	14 Dec 2020 15:32:40

US3482302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '14 Dec 2020'	(b) (4) Sarah Bechnak (b) (4)	14 Dec 2020 15:32:40
	(b) (4)	

US3482302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:32:40

US3482302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'VISIT3'	System	14 Dec 2020 15:32:40

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered empty.	System	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered empty.	System	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered empty.	System	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered empty.	System	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered empty.	System	14 Dec 2020 15:33:17

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11

US3482302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11

US3482302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:23

US3482302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:33:23

US3482302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:36:04

US3482302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '14 Dec 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:36:04

US3482302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered '09:30'	(b) (4) Sarah Bechnak (b) (4)	14 Dec 2020 15:36:04

US3482302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered '14 Dec 2020 09:30'	System	14 Dec 2020 15:36:04

US3482302

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:40:35
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Dec 2020 15:36:21

US3482302

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'I'	System	14 Dec 2020 15:36:21

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2020-12-17T09:05:36', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '0b6c347a-eac9-45b2-882f-d34315173d11'	System	17 Dec 2020 14:06:20
User entered 'No (N)'	System	17 Dec 2020 14:06:20

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2020-12-17T09:05:48', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '0b6c347a-eac9-45b2-882f-d34315173d11'	System	17 Dec 2020 14:06:20
User entered 'No (N)'	System	17 Dec 2020 14:06:20

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-12-17T09:06:14', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '0b6c347a-eac9-45b2-882f-d34315173d11'	System	17 Dec 2020 14:06:20
User entered '17 Dec 2020 09:06:14'	System	17 Dec 2020 14:06:20

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2020-12-23T10:33:54', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'bc07c85e-8386-4c92-a52e-f9d254d78d64'	System	23 Dec 2020 15:34:19
User entered 'No (N)'	System	23 Dec 2020 15:34:19

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2020-12-23T10:34:02', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'bc07c85e-8386-4c92-a52e-f9d254d78d64'	System	23 Dec 2020 15:34:19
User entered 'No (N)'	System	23 Dec 2020 15:34:19

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-12-23T10:34:16', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'bc07c85e-8386-4c92-a52e-f9d254d78d64'	System	23 Dec 2020 15:34:19
User entered '23 Dec 2020 10:34:16'	System	23 Dec 2020 15:34:19

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2020-12-30T10:02:06', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '63cebc4a-de96-4ac1-ac81-197392ff92b5'	System	30 Dec 2020 15:02:30
User entered 'No (N)'	System	30 Dec 2020 15:02:30

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2020-12-30T10:02:18', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '63cebc4a-de96-4ac1-ac81-197392ff92b5'	System	30 Dec 2020 15:02:30
User entered 'No (N)'	System	30 Dec 2020 15:02:30

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2020-12-30T10:02:26', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '63cebc4a-de96-4ac1-ac81-197392ff92b5' User entered '30 Dec 2020 10:02:26'	System	30 Dec 2020 15:02:30
	System	30 Dec 2020 15:02:30

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-01-06T23:00:20', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8d7de7f4-3242-4c65-bec2-fceac329cee5'	System	07 Jan 2021 04:00:36
User entered 'No (N)'	System	07 Jan 2021 04:00:36

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-01-06T23:00:24', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8d7de7f4-3242-4c65-bec2-fceac329cee5'	System	07 Jan 2021 04:00:36
User entered 'No (N)'	System	07 Jan 2021 04:00:36

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-01-06T23:00:31', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8d7de7f4-3242-4c65-bec2-fceac329cee5'	System	07 Jan 2021 04:00:36
User entered '06 Jan 2021 23:00:31'	System	07 Jan 2021 04:00:36

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-01-13T21:22:17', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '57d81c22-9065-4377-b7f1-648171687ff0'	System	14 Jan 2021 02:22:40
User entered 'No (N)'	System	14 Jan 2021 02:22:40

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-01-13T21:22:27', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '57d81c22-9065-4377-b7f1-648171687ff0'	System	14 Jan 2021 02:22:40
User entered 'No (N)'	System	14 Jan 2021 02:22:40

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-01-13T21:22:37', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '57d81c22-9065-4377-b7f1-648171687ff0'	System	14 Jan 2021 02:22:40
User entered '13 Jan 2021 21:22:37'	System	14 Jan 2021 02:22:40

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-01-23T19:25:51', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18998ee3-2cec-4f70-938b-64e4b2a6a3fa'	System	24 Jan 2021 00:27:07
User entered 'Yes (Y)'	System	24 Jan 2021 00:27:07

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-01-23T19:25:58', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18998ee3-2cec-4f70-938b-64e4b2a6a3fa'	System	24 Jan 2021 00:27:07
User entered 'Yes (Y)'	System	24 Jan 2021 00:27:07

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-01-23T19:26:13', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18998ee3-2cec-4f70-938b-64e4b2a6a3fa'	System	24 Jan 2021 00:27:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 00:27:07

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-01-23T19:26:29', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18998ee3-2cec-4f70-938b-64e4b2a6a3fa'	System	24 Jan 2021 00:27:07
User entered 'No (N)'	System	24 Jan 2021 00:27:07

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-01-23T19:26:46', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18998ee3-2cec-4f70-938b-64e4b2a6a3fa'	System	24 Jan 2021 00:27:07
User entered 'No (N)'	System	24 Jan 2021 00:27:07

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-01-23T19:26:55', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '18998ee3-2cec-4f70-938b-64e4b2a6a3fa'	System	24 Jan 2021 00:27:07
User entered '23 Jan 2021 19:26:55'	System	24 Jan 2021 00:27:07

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-02-18T10:09:42', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5c189294-38bc-4f42-8e7d-bc2969cc5474'	System	18 Feb 2021 15:10:07
User entered 'No (N)'	System	18 Feb 2021 15:10:07

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-02-18T10:09:50', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5c189294-38bc-4f42-8e7d-bc2969cc5474'	System	18 Feb 2021 15:10:07
User entered 'No (N)'	System	18 Feb 2021 15:10:07

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-02-18T10:09:59', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5c189294-38bc-4f42-8e7d-bc2969cc5474'	System	18 Feb 2021 15:10:07
User entered '18 Feb 2021 10:09:59'	System	18 Feb 2021 15:10:07

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-02-28T01:01:44-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f3902551-3f62-4b74-91d6-fbe2c691f8f5' User entered 'No (N)'	System	28 Feb 2021 06:02:23
	System	28 Feb 2021 06:02:23

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-02-28T01:01:50-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f3902551-3f62-4b74-91d6-fbe2c691f8f5'	System	28 Feb 2021 06:02:23
User entered 'No (N)'	System	28 Feb 2021 06:02:23

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-02-28T01:01:58-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'f3902551-3f62-4b74-91d6-fbe2c691f8f5' User entered '28 Feb 2021 01:01:58'	System	28 Feb 2021 06:02:23
	System	28 Feb 2021 06:02:23

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-03-03T00:03:10-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9a9f7701-3d99-46d1-a6e1-848fa8913bde'	System	03 Mar 2021 05:04:57
User entered 'No (N)'	System	03 Mar 2021 05:04:57

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-03-03T00:03:25-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9a9f7701-3d99-46d1-a6e1-848fa8913bde'	System	03 Mar 2021 05:04:57
User entered 'No (N)'	System	03 Mar 2021 05:04:57

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-03-03T00:03:40-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '9a9f7701-3d99-46d1-a6e1-848fa8913bde' User entered '03 Mar 2021 00:03:40'	System	03 Mar 2021 05:04:57
	System	03 Mar 2021 05:04:57

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-03-11T07:46:39-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c7d29c70-96a8-412d-9293-01b32221fe7a'	System	11 Mar 2021 12:47:21
User entered 'No (N)'	System	11 Mar 2021 12:47:21

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-03-11T07:47:06-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c7d29c70-96a8-412d-9293-01b32221fe7a'	System	11 Mar 2021 12:47:21
User entered 'No (N)'	System	11 Mar 2021 12:47:21

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-03-11T07:47:18-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c7d29c70-96a8-412d-9293-01b32221fe7a'	System	11 Mar 2021 12:47:21
User entered '11 Mar 2021 07:47:18'	System	11 Mar 2021 12:47:21

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-03-21T10:47:21-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c67ace36-57bb-427f-9462-61070eb1b024'	System	21 Mar 2021 14:47:37
User entered 'No (N)'	System	21 Mar 2021 14:47:37

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-03-21T10:47:28-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c67ace36-57bb-427f-9462-61070eb1b024'	System	21 Mar 2021 14:47:37
User entered 'No (N)'	System	21 Mar 2021 14:47:37

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-03-21T10:47:35-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'c67ace36-57bb-427f-9462-61070eb1b024' User entered '21 Mar 2021 10:47:35'	System	21 Mar 2021 14:47:37
	System	21 Mar 2021 14:47:37

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-04-01T06:09:35-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '46e0e874-a7ce-47f9-b795-7be7dabd9681'	System	01 Apr 2021 10:09:57
User entered 'No (N)'	System	01 Apr 2021 10:09:57

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-04-01T06:09:47-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '46e0e874-a7ce-47f9-b795-7be7dabd9681' User entered 'No (N)'	System	01 Apr 2021 10:09:57
	System	01 Apr 2021 10:09:57

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-04-01T06:09:54-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '46e0e874-a7ce-47f9-b795-7be7dabd9681' User entered '01 Apr 2021 06:09:54'	System	01 Apr 2021 10:09:57
	System	01 Apr 2021 10:09:57

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-04-14T00:04:52-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8a787a25-eb20-4beb-b2cb-5bc72d103092'	System	14 Apr 2021 04:06:38
User entered 'No (N)'	System	14 Apr 2021 04:06:38

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-04-14T00:05:01-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8a787a25-eb20-4beb-b2cb-5bc72d103092'	System	14 Apr 2021 04:06:38
User entered 'No (N)'	System	14 Apr 2021 04:06:38

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-04-14T00:05:16-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '8a787a25-eb20-4beb-b2cb-5bc72d103092'	System	14 Apr 2021 04:06:38
User entered '14 Apr 2021 00:05:16'	System	14 Apr 2021 04:06:38

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-04-21T09:34:48-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '80db4cde-a533-476c-a6d2-d3af33becc17'	System	21 Apr 2021 13:35:08
User entered 'No (N)'	System	21 Apr 2021 13:35:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-04-21T09:34:56-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '80db4cde-a533-476c-a6d2-d3af33becc17'	System	21 Apr 2021 13:35:08
User entered 'No (N)'	System	21 Apr 2021 13:35:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-04-21T09:35:02-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '80db4cde-a533-476c-a6d2-d3af33becc17'	System	21 Apr 2021 13:35:08
User entered '21 Apr 2021 09:35:02'	System	21 Apr 2021 13:35:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[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 (31465f9fc8c0cdc6)', Time: '2021-05-01T10:22:40-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd24b3b8d-af4f-4434-b4cc-b7950fae3d3e'	System	01 May 2021 14:23:15
User entered 'No (N)'	System	01 May 2021 14:23:15

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

Have you been exposed to someone with 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 (31465f9fc8c0cdc6)', Time: '2021-05-01T10:23:00-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd24b3b8d-af4f-4434-b4cc-b7950fae3d3e'	System	01 May 2021 14:23:15
User entered 'No (N)'	System	01 May 2021 14:23:15

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-05-01T10:23:11-04:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: 'd24b3b8d-af4f-4434-b4cc-b7950fae3d3e'	System	01 May 2021 14:23:15
User entered '01 May 2021 10:23:11'	System	01 May 2021 14:23:15

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '07 Dec 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '11 Dec 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '14 Dec 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '18 Dec 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '21 Dec 2022 00:01'	System	20 Nov 2020 13:05:08

US3482302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:05:08
Amendment Manager: User entered '25 Dec 2022 23:59'	System	20 Nov 2020 13:05:08

US3482302

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:44:55

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 13:07:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-02-28T01:02:20-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5e510980-7c6a-481d-970a-b7e0f09cb73a'	System	28 Feb 2021 06:03:14
User entered 'No (N)'	System	28 Feb 2021 06:03:14

US3482302

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:44:55

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:07:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31465f9fc8c0cdc6)', Time: '2021-02-28T01:02:32-05:00', User OID: 'PatientReportedOutcome (US3482302)', ODM File OID: '5e510980-7c6a-481d-970a-b7e0f09cb73a' User entered '28 Feb 2021 01:02:32'	System	28 Feb 2021 06:03:14
	System	28 Feb 2021 06:03:14

US3482302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:28:55

US3482302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:28:55

US3482302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:28:55

US3482302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:28:55

US3482302

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:28:45

US3482302

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:11
User entered 'I'	System	01 Feb 2021 15:28:45

US3482302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 11:25:48

US3482302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 11:25:48

US3482302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 11:25:48

US3482302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 11:25:48

US3482302

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 11:26:10

US3482302

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User entered 'I'	System	17 Mar 2021 11:26:10

US3482302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 00:30:42

US3482302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 00:30:42

US3482302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 00:30:42

US3482302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 00:30:42

US3482302

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 00:30:47

US3482302

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:53
User entered 'I'	System	01 Apr 2021 00:30:47

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:55

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:06:50
User entered '14 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:11:40

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:55

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:15:43
User closed query 'Per source, the time patient seated was 0825pm. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:15:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
Query 'Per source, the time patient seated was 0825pm. Please confirm and update.' answered with 'PARTICIPANT SEATED AT 0830AM PER NOTES FROM ORIGINAL NURSE FOR DECISION VISIT THAT MORNING. THIS ILLNESS VISIT RESULTED FROM A DECISION VISIT WHERE THE PPT WAS FOUND TO BE ILL/FEBRILE UPON ARRIVAL. ORIGINAL DECISION VISIT DCF IN SOURCE.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Mar 2021 02:25:22
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 22:06:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:06:50
User opened query 'Per source, the time patient seated was 0825pm. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 22:06:46
User entered '08:30'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:11:40

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:55

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:14
User entered '14 Jan 2021 08:30'	System	14 Jan 2021 20:11:40

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:55

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:15:43
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Mar 2021 02:23:52
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Mar 2021 02:23:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:06:50
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:11:40

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:55

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:06:50
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:11:40

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User closed query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:32:44
Query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Source doc filed' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	20 Apr 2021 19:19:59
User opened query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 1 (Day 1)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '11 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 14:49:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:31:26
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 19:14:02
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:02
User entered '0' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '1'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	14 Jan 2021 20:14:16
User entered empty.	System	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '100.4' F reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	14 Jan 2021 20:14:16
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:12:07

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User closed query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:32:48
Query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Source doc filed' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	20 Apr 2021 19:20:04
User opened query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:22:47
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 2 (Day 2)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '12 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 14:49:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:31:26
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 19:14:02
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:02
User entered '0' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '1'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered missing code ND - Not Done.	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '100.4' F	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:15:24

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User closed query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:32:53
Query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Source doc filed' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	20 Apr 2021 19:20:08
User opened query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:22:56
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 3 (Day 3)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '13 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 14:49:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:31:26
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 19:14:02
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:02
User entered '0' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '1'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered missing code ND - Not Done.	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '100.4' F	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Not Done (Not Done)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:16:50

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 4 (Day 4)'	Joy Winters (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '14 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '99'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '99' F	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:18:14

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 5 (Day 5)'	(b) (4) Michelle Wiles (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '15 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '95' reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Jan 2021 00:00:23
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	16 Jan 2021 00:00:23
User entered empty.	System	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '100.4' F reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Jan 2021 00:00:23
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:19:43

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 6 (Day 6)'	(b) (4) Lauren Hewitt (b) (4)	17 Jan 2021 22:45:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '16 Jan 2021'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '99'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	17 Jan 2021 22:45:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '99.7' F	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:45:18

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 7 (Day 7)'	(b) (4) Lauren Hewitt (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '17 Jan 2021'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '97'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '100.0' F	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:47:55

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 8 (Day 8)'	(b) (4) Michelle Wiles (b) (4)	19 Jan 2021 21:25:38

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '18 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '94' reason for change: Data Entry Error	Michelle Wiles (b) (4)	19 Jan 2021 21:27:33
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	19 Jan 2021 21:27:33
User entered empty.	System	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '100.0' F	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	19 Jan 2021 21:27:33
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	19 Jan 2021 21:27:33
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:25:38

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 9 (Day 9)'	(b) (4) Michelle Wiles (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '19 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '94' reason for change: Data Entry Error	Michelle Wiles (b) (4)	20 Jan 2021 19:13:45
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	20 Jan 2021 19:13:45
User entered empty.	System	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '100.0' F	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 21:26:56

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 10 (Day 10)'	(b) (4) Michelle Wiles (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '20 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '91'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '102.1' F	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:43:13

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 11 (Day 11)'	(b) (4) Michelle Wiles (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '21 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '86'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '99.5' F	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:41

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User closed query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:34:47
Query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Temperature and O2 obtained from hospital records, no other assessments obtained, PD filed.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	20 Apr 2021 19:16:43
User opened query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:23:16
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 12 (Day 12)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:52

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '22 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:52

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 14:49:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:27:02
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 19:14:15
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:15
User entered '0' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:15
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '1'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:29:52

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:41:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:27:04
User closed query 'Per source, patients O2 sat and Temp were obtained while hospitalized. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:17:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
Query 'Per source, patients O2 sat and Temp were obtained while hospitalized. Please confirm and update.' answered with 'updated' (Site from CRA).	(b) (4)	
User entered '93' reason for change: Data Entry Error	Michelle Wiles (b) (4)	26 Mar 2021 17:38:41
User opened query 'Per source, patients O2 sat and Temp were obtained while hospitalized. Please confirm and update.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 18:37:07
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	17 Mar 2021 18:36:20
	(b) (4), (b) (6)	17 Mar 2021 15:26:11
	(b) (4), (b) (6)	
	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	26 Mar 2021 17:36:42
User entered empty.	System	26 Jan 2021 19:29:52

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:27:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '36.6' C reason for change: New Information	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:38:31
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 18:36:22
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:36:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:29:52
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User closed query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:34:51
Query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Temperature and O2 obtained from hospital records, no other assessments obtained, PD filed.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	20 Apr 2021 19:16:52
User opened query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:23:28
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 13 (Day 13)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:30:01

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '23 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:30:01

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 14:49:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:31:26
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 19:14:15
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:15
User entered '0' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:15
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '1'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:30:01

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User closed query 'Per source, patients O2 sat and Temp were obtained while hospitalized. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:27:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
Query 'Per source, patients O2 sat and Temp were obtained while hospitalized. Please confirm and update.' answered with 'updated' (Site from CRA).	(b) (4)	
User entered '94' reason for change: Data Entry Error	Michelle Wiles (b) (4)	26 Mar 2021 17:40:37
User opened query 'Per source, patients O2 sat and Temp were obtained while hospitalized. Please confirm and update.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:37:40
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 18:37:11
	(b) (4), (b) (6)	17 Mar 2021 15:26:11
	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	26 Mar 2021 17:40:24
User entered empty.	System	26 Jan 2021 19:30:01

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '36.7' C reason for change: New Information	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 18:37:13
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Form: Symptom Log (13)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:40:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:01
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User closed query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:34:57
Query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Temperature and O2 obtained from hospital records, no other assessments obtained, PD filed.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	20 Apr 2021 19:17:01
User opened query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 14 Jan 2021 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:23:37
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 14 (Day 14)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:30:10

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '24 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:30:10

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 14:49:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:31:26
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 19:14:15
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:15
User entered '0' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 19:14:15
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '1' reason for change: Data Entry Error	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
User entered '0'	(b) (4) Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:35:05
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User closed query 'Per source, patients O2 sat and Temp were obtained while hospitalized. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:27:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
Query 'Per source, patients O2 sat and Temp were obtained while hospitalized. Please confirm and update.' answered with 'updated' (Site from CRA).	(b) (4)	
User entered '90' reason for change: Data Entry Error	Michelle Wiles (b) (4)	26 Mar 2021 17:42:06
User opened query 'Per source, patients O2 sat and Temp were obtained while hospitalized. Please confirm and update.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:38:02
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 18:37:46
	(b) (4), (b) (6)	17 Mar 2021 15:26:11
	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	26 Mar 2021 17:41:58
User entered empty.	System	26 Jan 2021 19:30:10

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '36.5' C reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 18:37:48
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Form: Symptom Log (14)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Form: Symptom Log (14)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:10
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 14 Jan 2021 symptom log on log line 15. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:35:01
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 14 Jan 2021 symptom log on log line 15. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Temperature and O2 obtained from hospital records, no other assessments obtained, PD filed.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	20 Apr 2021 19:16:19
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 14 Jan 2021 symptom log on log line 15. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:23:49
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 15 (Day 15)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:30:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '25 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:30:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:30:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '1'		
	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:20
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '93' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:38:07
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	(b) (4)	
	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	26 Mar 2021 17:43:06
User entered empty.	System	26 Jan 2021 19:30:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:01
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 18:38:09
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:03
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:31:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Un-verified.	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	26 Mar 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered empty.	Michelle Wiles (b) (4)	26 Jan 2021 19:30:25
	(b) (4)	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 16 (Day 16)'	(b) (4) Michelle Wiles (b) (4)	26 Jan 2021 19:31:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '26 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '94'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	26 Jan 2021 19:31:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '98.4' F	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	26 Jan 2021 19:31:25

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Day 17 (Day 17)'	(b) (4) Michelle Wiles (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '27 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '0'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '97'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User entered '%'	System	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered '97.8' F	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:26:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	27 Jan 2021 18:58:00

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:55

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:04:47
User entered '14 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:19:16

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:55

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:04:47
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:19:16

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:55

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:04:47
User closed query 'Please complete COVID-19 Severity Assessment page as required.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 21:43:39
Query 'Please complete COVID-19 Severity Assessment page as required.' answered with 'Partially completed. Was rehospitalized for COVID.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 14:36:46
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 13:56:03
User opened query 'Please complete COVID-19 Severity Assessment page as required.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 23:17:06
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 'UPDATED' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 18:38:22
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 18:38:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 18:38:13
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	22 Jan 2021 18:38:13
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	22 Jan 2021 18:38:13
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 20:19:16
User entered empty.	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:19:16

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:55

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:04:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is under Illness visit in PPD Central lab. Please review the correct visit and update accordingly.Thanks' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 05:17:23
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is under Illness visit in PPD Central lab. Please review the correct visit and update accordingly.Thanks' answered with 'Saliva positive received before NP PCR positive. Updated.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 14:37:46
User entered '14 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	04 Feb 2021 14:37:33
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is under Illness visit in PPD Central lab. Please review the correct visit and update accordingly.Thanks' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 07:50:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Covid-19 Assessment 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)	03 Feb 2021 07:44:48

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:55

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Covid-19 Assessment 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)	01 Feb 2021 04:40:37
User entered '16 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	22 Jan 2021 18:38:13
User entered '14 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:19:16

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:55

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:04:47
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: New Information	(b) (4), (b) (6)	04 Feb 2021 14:37:33
User entered 'Saliva Test (Saliva Test)' reason for change: New Information	(b) (4), (b) (6)	22 Jan 2021 18:38:13
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:19:16

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:55

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:04:47
User entered empty.	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:19:16

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

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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)	03 May 2021 13:03:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:04:47
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:19:16

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:04:47
User entered empty.	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:19:16

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:04:47
User entered empty.	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:19:16

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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:32
User entered 'I'	System	22 Jan 2021 18:38:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:54:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 15:54:23
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:54:23
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 15:43:57
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:54:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 15:54:23
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:54:23
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 15:43:57
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Form: Covid-19 Severity Assessment

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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)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered '20 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:52
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 15 (25Jan2021), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:38
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 15 (25Jan2021), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' answered with 'Updated per source.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	21 Apr 2021 13:45:00
Signature has been broken.	Michelle Wiles (b) (4) (b) (4)	21 Apr 2021 13:44:37
User entered '25 Jan 2021' reason for change: Per Query Resolution	Michelle Wiles (b) (4) (b) (4)	21 Apr 2021 13:44:37
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 15 (25Jan2021), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:47:39
User closed query 'Per CDM: Per sponsor review, please provide end date of Low O2. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 23:24:55
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	08 Apr 2021 16:23:46
Query 'Per CDM: Per sponsor review, please provide end date of Low O2. ' answered with 'Updated with end date.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:27:56
DataPoint Un-verified.	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:27:46
User entered '23 Jan 2021' reason for change: Per Query Resolution	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:27:46
User opened query 'Per CDM: Per sponsor review, please provide end date of Low O2. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 17:56:39
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:05:26

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EAB) (1725)

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[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered '86'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Generated On: 09 Jun 2021 17:44:55

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:54:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 15:54:23
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:54:23
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 15:43:57
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:54:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 15:54:23
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:54:23
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 15:43:57
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:54:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 15:54:23
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:54:23
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 15:43:57
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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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)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

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Generated On: 09 Jun 2021 17:44:55

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Feb 2021 15:54:23
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Feb 2021 15:54:23
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Feb 2021 15:54:23
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered '21 Jan 2021' reason for change: New Information	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:54:23
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Feb 2021 15:54:23
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Feb 2021 15:54:23
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered 'Yes (Y)' reason for change: New Information	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:54:23
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered '21 Jan 2021' reason for change: New Information	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:54:23
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Feb 2021 15:54:23
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered '21 Jan 2021' reason for change: Per Query Resolution	Michelle Wiles (b) (4)	16 Feb 2021 15:54:23
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:54:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 15:54:23
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:54:23
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 15:43:57
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Covid-19 Assessment 14 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:46
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:05:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:43:57

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered '16 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this DAY 5 SALIVA sample is recorded as collected on 19 JAN 2021 , however in EDC, it is recorded as collected on 18 JAN 2021. Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 05:38:02
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this DAY 5 SALIVA sample is recorded as collected on 19 JAN 2021 , however in EDC, it is recorded as collected on 18 JAN 2021. Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' answered with 'SPECIMEN WAS COLLECTED BY PATIENT LATE IN DAY ON 18JAN 2021 BUT PICKED UP BY COURIER ON 19JAN. PICKUP DELAYED DUE TO LAB CLOSURE ON MLK HOLIDAY 18JAN 2021.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 22:32:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this DAY 5 SALIVA sample is recorded as collected on 19 JAN 2021 , however in EDC, it is recorded as collected on 18 JAN 2021. Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 20:48:23
User entered '18 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered '20 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered '27 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User closed query 'Per GCL Lab Reconciliation: Saliva collection: Please consider checking YES/NO for Was Saliva Collected? and if YES, consider recording date of collection. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 09:59:00
Query 'Per GCL Lab Reconciliation: Saliva collection: Please consider checking YES/NO for Was Saliva Collected? and if YES, consider recording date of collection. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 22:26:15
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 22:25:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 22:25:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 22:25:53
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 17:21:02
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User opened query 'Per GCL Lab Reconciliation: Saliva collection: Please consider checking YES/NO for Was Saliva Collected? and if YES, consider recording date of collection. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:41:51
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 15:16:09
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:55

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:28
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 22:25:53
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 17:21:04
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:20:32
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 15:16:09

US3482302

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:07:40
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:08:59

US3482302

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:07:40
User entered '14 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:08:59

US3482302

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[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 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:07:40
User entered 'Clinic (Clinic)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:08:59

US3482302

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User entered 'SICKD1'	System	14 Jan 2021 20:08:59

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
User closed query 'Per CDM: Illness Visit Day 1 and Participant Decision Visit / OL-D1 are both dated 14Jan2021, however the data on both the visits vitals page doesn't match. Please reconcile and update as appropriate else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:14
Query 'Per CDM: Illness Visit Day 1 and Participant Decision Visit / OL-D1 are both dated 14Jan2021, however the data on both the visits vitals page doesn't match. Please reconcile and update as appropriate else clarify. ' answered with 'Subject OL-D1 converted to illness visit. Vitals on OL-D1 are from vaccination visit after he recovered from COVID. Date is correct as written.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:26:13
User opened query 'Per CDM: Illness Visit Day 1 and Participant Decision Visit / OL-D1 are both dated 14Jan2021, however the data on both the visits vitals page doesn't match. Please reconcile and update as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 09:06:34
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered '14 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered '10:04'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User entered '14 Jan 2021 10:04'	System	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered missing code ND - Not Done.	Joy Winters (b) (4)	14 Jan 2021 20:10:14
DataPoint set to visible.	(b) (4) System	14 Jan 2021 20:08:59

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered missing code ND - Not Done.	Joy Winters (b) (4)	14 Jan 2021 20:10:14
DataPoint set to visible.	(b) (4) System	14 Jan 2021 20:08:59

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Jan 2021 20:10:22
User entered '99' F reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Jan 2021 20:10:14
User entered '99' (non-conformant).	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered 'Oral (Oral)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered empty.	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered '66'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User entered 'bpm'	System	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered '16'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User entered 'breaths/min'	System	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered '131'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User entered 'mmHg'	System	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:09:31
User entered '75'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User entered 'mmHg'	System	14 Jan 2021 20:10:14

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07

US3482302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07

US3482302

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:19:12
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:35

US3482302

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:19:12
User entered '14 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:35

US3482302

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:44:55

[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 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:19:20
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:54

US3482302

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:44:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:19:20
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). Query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'Accession #1F60N0K. See lab query response in Preclarus.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 09:28:19
Query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'Accession #1F60N0K. See lab query response in Preclarus.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 14:35:04
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 10:31:12
User entered '14 Jan 2021'	Joy Winters (b) (4) (b) (4)	14 Jan 2021 20:10:54

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:04
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:41:53

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:04
User entered '15 Feb 2021'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:41:53

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[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 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:04
User entered 'Clinic (Clinic)'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:41:53

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'SICKD28'	System	15 Feb 2021 15:41:53

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered '15 Feb 2021'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered '09:37'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered '15 Feb 2021 09:37'	System	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered missing code ND - Not Done.	Michelle Wiles (b) (4)	15 Feb 2021 15:43:19
DataPoint set to visible.	(b) (4) System	15 Feb 2021 15:41:53

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered missing code ND - Not Done.	Michelle Wiles (b) (4)	15 Feb 2021 15:43:19
DataPoint set to visible.	(b) (4) System	15 Feb 2021 15:41:53

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered '98.3' F	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered 'Oral (Oral)'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered empty.	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered '81'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'bpm'	System	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered '16'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'breaths/min'	System	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered '129'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'mmHg'	System	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:24:28
User entered '74'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'mmHg'	System	15 Feb 2021 15:43:19

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:57
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:42:03

US3482302

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:57
User entered '15 Feb 2021'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:42:03

US3482302

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:44:55

[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 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:47
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:42:16

US3482302

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:44:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:47
User entered '15 Feb 2021'	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:42:16

US3482302

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

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:40:41

US3482302

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

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '14 Jan 2021'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 14:40:41

US3482302

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

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:40:41

US3482302

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

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 14:40:41

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '14 Jan 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:40:56

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:38:03

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 14:40:56

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
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 15:38:03

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '14 Jan 2021'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 14:40:56

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Placebo (Placebo)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:40:56

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 10:01:50
User entered 'Placebo (Placebo)'	Sarah Bechnak (b) (4)	14 Jan 2021 14:40:56
	(b) (4)	

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 10:01:50
User entered 'Placebo (Placebo)'	Sarah Bechnak (b) (4)	14 Jan 2021 14:40:56
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	19 Feb 2021 20:51:18
User entered 'No (N)'	(b) (4)	
	Sarah Bechnak (b) (4)	14 Jan 2021 14:40:56
	(b) (4)	

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered '1'	System	14 Jan 2021 14:40:56

US3482302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'I'	System	19 Feb 2021 20:51:18
User entered empty.	System	14 Jan 2021 14:40:56

US3482302

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered empty.	System	19 Feb 2021 20:52:38
DataPoint set to visible.	System	19 Feb 2021 20:51:18

US3482302

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered empty.	System	19 Feb 2021 20:52:38
DataPoint set to visible.	System	19 Feb 2021 20:51:18

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User accepted default value 'Pre-Dose (PREDOSE)'	Michelle Wiles (b) (4) (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '19 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '14:47'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered '19 Feb 2021 14:47'	System	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '98.3' F	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Oral (Oral)'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '80'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'bpm'	System	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '17'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'breaths/min'	System	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '112'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'mmHg'	System	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '67'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'mmHg'	System	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered empty.	System	19 Feb 2021 20:52:38
DataPoint set to visible.	System	19 Feb 2021 20:51:18

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User accepted default value 'Post-Dose (POSTDOSE)'	Michelle Wiles (b) (4) (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '19 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '15:36'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered '19 Feb 2021 15:36'	System	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '98.2' F	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 20:52:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Feb 2021 20:52:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	19 Feb 2021 20:52:47
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 20:52:38
User entered empty.	System	19 Feb 2021 20:52:38
	Michelle Wiles (b) (4)	19 Feb 2021 20:52:38
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '80'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'bpm'	System	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '16'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'breaths/min'	System	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '114'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'mmHg'	System	19 Feb 2021 20:52:38

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '70'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:38

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'mmHg'	System	19 Feb 2021 20:52:38

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:58

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '19 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:52:58

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:53:29

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:53:29

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

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)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:53:29

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'mRNA-1273'	System	19 Feb 2021 20:53:29
DataPoint set to visible.	System	19 Feb 2021 20:51:18

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '19 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:53:29

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '15:05'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:53:29

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered '19 Feb 2021 15:05'	System	19 Feb 2021 20:53:29

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:53:29

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'ONCE'	System	19 Feb 2021 20:53:29

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 20:53:29

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:41:09

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '14 Jan 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:41:09

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '08:40'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:41:09

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered '14 Jan 2021 08:40'	System	14 Jan 2021 14:41:09

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:41:20

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per EDC, swab sample was collected on 14-JAN-2021 at Covid-19 Assessment visit and at Participant Decision Visit/OL-D1 visit; however, per site response & per PPD portal, it is present under Illness visit. Kindly consider updating EDC as appropriate as swab sample is duplicating in EDC, else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 09:51:06
Query 'Per GCL Lab Reconciliation requery: Swab: Per EDC, swab sample was collected on 14-JAN-2021 at Covid-19 Assessment visit and at Participant Decision Visit/OL-D1 visit; however, per site response & per PPD portal, it is present under Illness visit. Kindly consider updating EDC as appropriate as swab sample is duplicating in EDC, else clarify' answered with 'Swab collected at OL-D1 visit that was converted to an illness visit, per monitor, not additional swab collected.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	24 Mar 2021 18:27:58
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per EDC, swab sample was collected on 14-JAN-2021 at Covid-19 Assessment visit and at Participant Decision Visit/OL-D1 visit; however, per site response & per PPD portal, it is present under Illness visit. Kindly consider updating EDC as appropriate as swab sample is duplicating in EDC, else clarify' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:23:12
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is recorded under Participant Decision Visit / OL-D1 in EDC; however, the swab sample for 14-JAN-2021 is reported under Illness visit in PPD portal. Please reconcile the correct visit and update if applicable in EDC or Preclarus, else clarify the correct visit name in site response.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:23:12

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is recorded under Participant Decision Visit / OL-D1 in EDC; however, the swab sample for 14-JAN-2021 is reported under Illness visit in PPD portal. Please reconcile the correct visit and update if applicable in EDC or Preclarus, else clarify the correct visit name in site response.' answered with 'Decision visit was switched to illness visit. ' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 17:13:05
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is recorded under Participant Decision Visit / OL-D1 in EDC; however, the swab sample for 14-JAN-2021 is reported under Illness visit in PPD portal. Please reconcile the correct visit and update if applicable in EDC or Preclarus, else clarify the correct visit name in site response.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:46:13
User entered '14 Jan 2021'	Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:41:20

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '08:45'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 14:41:20

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered '14 Jan 2021 08:45'	System	14 Jan 2021 14:41:20

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	19 Feb 2021 20:53:34

US3482302

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:17
User entered 'I'	System	19 Feb 2021 20:53:34

US3482302

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:01
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	02 Mar 2021 13:55:45

US3482302

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:01
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '01 Mar 2021'	(b) (4) Michelle Wiles (b) (4)	02 Mar 2021 13:55:45

US3482302

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:01
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michelle Wiles (b) (4)	02 Mar 2021 13:55:45

US3482302

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:01
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4)	02 Mar 2021 13:55:45

US3482302

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:01
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	02 Mar 2021 13:55:51

US3482302

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:01
User entered 'I'	System	02 Mar 2021 13:55:51

US3482302

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:01
User entered 'I'	System	02 Mar 2021 13:55:51
DataPoint set to visible.	System	02 Mar 2021 13:55:51

US3482302

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:34:08

US3482302

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	16 Mar 2021 15:34:21
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	16 Mar 2021 15:34:21
User entered '16 Mar 2021' reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Mar 2021 15:34:21
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	16 Mar 2021 15:34:08
User entered '06 Mar 2021'	System	16 Mar 2021 15:34:08
	Michelle Wiles (b) (4)	16 Mar 2021 15:34:08
	(b) (4)	

US3482302

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Clinic (Clinic)'	Michelle Wiles (b) (4)	16 Mar 2021 15:34:08

US3482302

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'OLD29'	System	16 Mar 2021 15:34:08

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User accepted default value 'Pre-Dose (PREDOSE)'	Michelle Wiles (b) (4) (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '16 Mar 2021'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '10:04'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered '16 Mar 2021 10:04'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '98.2' F	Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Oral (Oral)'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '84'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'bpm'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '16'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'breaths/min'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '118'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'mmHg'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '70'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'mmHg'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User accepted default value 'Post-Dose (POSTDOSE)'	Michelle Wiles (b) (4) (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '16 Mar 2021'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '11:15'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered '16 Mar 2021 11:15'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '97.8' F	Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Oral (Oral)'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '78'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'bpm'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '16'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'breaths/min'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '124'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'mmHg'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '67'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'mmHg'	System	16 Mar 2021 15:38:45

US3482302

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:34:34

US3482302

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '16 Mar 2021'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:34:34

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:35:05

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:35:05

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

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)	30 Apr 2021 14:48:38
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	16 Mar 2021 15:35:05

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'mRNA-1273'	System	16 Mar 2021 15:35:05
DataPoint set to visible.	System	02 Mar 2021 13:55:51

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '16 Mar 2021'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:35:05

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '10:42'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:35:05

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered '16 Mar 2021 10:42'	System	16 Mar 2021 15:35:05

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:35:05

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'ONCE'	System	16 Mar 2021 15:35:05

US3482302

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'INTRAMUSCULAR'	System	16 Mar 2021 15:35:05

US3482302

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	16 Mar 2021 15:37:01

US3482302

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:38
User entered 'I'	System	16 Mar 2021 15:37:01

US3482302

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	23 Mar 2021 14:43:36

US3482302

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '23 Mar 2021'	Michelle Wiles (b) (4)	23 Mar 2021 14:43:36

US3482302

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 14:43:36

US3482302

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered empty.	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 14:43:36

US3482302

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	23 Mar 2021 14:43:41

US3482302

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:17
User entered 'I'	System	23 Mar 2021 14:43:41

US3482302

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	13 Apr 2021 19:05:42
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered '12 Apr 2021'	Michelle Wiles (b) (4)	13 Apr 2021 19:05:42
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'Clinic (Clinic)'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:05:42

US3482302

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	13 Apr 2021 19:05:42

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered empty.	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:05:48

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:05:48

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:05:48

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:05:48

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:05:48
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:05:48

US3482302

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	13 Apr 2021 19:05:56
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:05:56
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	13 Apr 2021 19:06:09
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered '12 Apr 2021'	Michelle Wiles (b) (4)	13 Apr 2021 19:06:09
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered '10:06'	Michelle Wiles (b) (4)	13 Apr 2021 19:06:09
	(b) (4)	

US3482302

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 10:06'	System	13 Apr 2021 19:06:09

US3482302

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:44:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:54:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:26:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 15:10:53

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:25:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:50
User entered 'USA-US106-2021-mRNA-1273-P301000008'	System	29 Jan 2021 15:40:39
User entered 'New'	(b) (4), (b) (6)	29 Jan 2021 15:40:39

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:52
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)	28 Jan 2021 15:55:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 15:55:19
Data point term sent to Coder	System	28 Jan 2021 15:54:45
User entered 'COVID 19'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:54
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:55
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:57
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:13
User entered '11 Jan 2021'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:15
User entered empty.	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:00:59
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	15 Feb 2021 15:44:41
DataPoint Un-verified.	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:44:41
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	15 Feb 2021 15:44:41
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	15 Feb 2021 15:44:16
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:49:16
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:01:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 16:01:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 16:01:11
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 15:54:38
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 16:01:00
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 14:58:57
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'Event end date updated.' (Site from Safety).	Michelle Wiles (b) (4)	15 Feb 2021 15:45:35
	(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	15 Feb 2021 15:44:41
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	15 Feb 2021 15:44:41
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	15 Feb 2021 15:44:16
User entered '27 Jan 2021' reason for change: New Information	Michelle Wiles (b) (4)	15 Feb 2021 15:44:16
	(b) (4)	
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 23:53:26

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:49:21
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:49:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:24
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:26
User entered '0'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:27
User entered '0'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:49:29
User entered 'I'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:32
User entered '21 Jan 2021'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:49:33
User entered '25 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:49:35
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	01 Feb 2021 14:51:10 01 Feb 2021 14:51:10
User entered 'No (N)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	01 Feb 2021 14:51:10
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	28 Jan 2021 15:54:38
User entered 'Unknown (UNK)'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:37
User entered empty.	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:38
User entered '0'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:39
User entered '0'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:49:58
User entered '0'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:50:00
User entered 'Not Related (NOT RELATED)'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

US3482302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:50:05
User entered 'Not Related (NOT RELATED)'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:50:06
User entered 'Not Applicable (NOT APPLICABLE)'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

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None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:50:08
User entered '0'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:44:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 21:50:09
User entered 'I'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however consider recording SUPPLEMENTAL OXYGEN & CONVALESCENT PLASMA INFUSION in the Concomitant Medication eCRF and update the response as appropriate. Otherwise, clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4) Nadine Rouphael (b) (4)	29 Mar 2021 11:37:47 26 Mar 2021 22:34:27
Query 'Per DM CLR: Other Action Taken = Con Procedure, however consider recording SUPPLEMENTAL OXYGEN & CONVALESCENT PLASMA INFUSION in the Concomitant Medication eCRF and update the response as appropriate. Otherwise, clarify. ' answered with 'Neither are considered medications.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	26 Mar 2021 17:44:45
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however consider recording SUPPLEMENTAL OXYGEN & CONVALESCENT PLASMA INFUSION in the Concomitant Medication eCRF and update the response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:26:23
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:01:05
DataPoint Un-verified.	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:55:47
User entered '1' reason for change: New Information	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 15:55:47
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:50:11
User entered '0'	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 16:01:07
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 14:59:09
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'event updated' (Site from Safety).	Michelle Wiles (b) (4)	15 Feb 2021 15:45:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	15 Feb 2021 15:44:41
New Information		
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 21:50:20
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:50:12
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 23:54:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Michelle Wiles (b) (4)	28 Jan 2021 15:54:38
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:50:13
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:50:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Un-verified.	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:32:16
User entered 'SUBJECT BEING FOLLOWED FOR ILLNESS VISIT VIA TELEMEDICINE AFTER POSITIVE COVID TEST DURING ILLNESS VISIT. SUBJECT NOTED TO HAVE DECREASED O2 SATS (86-88%). SEND FOR CLINICAL EVALUATION, SENT TO ER WHERE HE WAS ADMITTED and placed on supplemental oxygen. AWAITING MEDICAL RECORDS FOR MORE INFORMATION. RT-PCR TEST DONE ON 21JAN2021 DURING THIS ADMISSION, POSITIVE.' reason for change: Data Entry Error	Michelle Wiles (b) (4)	26 Mar 2021 17:32:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:01:09
User closed query 'PV Query: Per discharge summary, the subject had a positive COVID test on 06 Jan 2021. Please confirm if the date reported is correct.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 18:37:20
Query 'PV Query: Per discharge summary, the subject had a positive COVID test on 06 Jan 2021. Please confirm if the date reported is correct.' answered with 'The date reported in the EDC is correct.' (Site from Safety).	Michelle Wiles (b) (4)	04 Mar 2021 13:35:46
User entered 'SUBJECT BEING FOLLOWED FOR ILLNESS VISIT VIA TELEMEDICINE after positive COVID test during illness visit. SUBJECT NOTED TO HAVE DECREASED O2 SATS (86-88%). SEND FOR CLINICAL EVALUATION, SENT TO ER WHERE HE WAS ADMITTED. AWAITING MEDICAL RECORDS FOR MORE INFORMATION. RT-PCR TEST DONE ON 21JAN2021 DURING THIS ADMISSION, POSITIVE.' reason for change: Data Entry Error	Michelle Wiles (b) (4)	04 Mar 2021 13:35:34
User opened query 'PV Query: Per discharge summary, the subject had a positive COVID test on 06 Jan 2021. Please confirm if the date reported is correct.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:59:12

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 17:11:29
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 17:11:25
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:24:47
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'added information to narrative.' (Site from Safety).	Michelle Wiles (b) (4)	17 Feb 2021 18:19:50
User entered 'SUBJECT BEING FOLLOWED FOR ILLNESS VISIT VIA TELEMEDICINE. SUBJECT NOTED TO HAVE DECREASED O2 SATS (86-88%). SEND FOR CLINICAL EVALUATION, SENT TO ER WHERE HE WAS ADMITTED. AWAITING MEDICAL RECORDS FOR MORE INFORMATION. RT-PCR test done on 21Jan2021 during this admission, positive.' reason for change: Data Entry Error	Michelle Wiles (b) (4)	17 Feb 2021 18:19:12
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Treatment added to con meds and con procedures.' (Site from Safety).	Michelle Wiles (b) (4)	17 Feb 2021 18:10:47

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EAB) (1725)

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Emailed to above address 2/13/2021 at 11:11am.' (Site from Safety).	Michelle Wiles (b) (4)	16 Feb 2021 16:12:04
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 23:54:11
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 23:53:42
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 23:53:05
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Jan 2021 16:01:11
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	28 Jan 2021 16:01:11
User entered 'Subject being followed for illness visit via telemedicine. Subject noted to have decreased O2 sats (86-88%). Send for clinical evaluation, sent to ER where he was admitted. Awaiting medical records for more information.' reason for change: Data Entry Error	Michelle Wiles (b) (4)	28 Jan 2021 16:01:11
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Jan 2021 15:54:38

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Michelle Wiles (b) (4) (b) (4)	28 Jan 2021 15:54:38

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 15:54:38

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Jan 2021 15:54:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Jan 2021 15:54:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:06:51
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:05:10
User entered		
'USA-US106-2021-mRNA-1273-P301000011'	System	17 Feb 2021 15:03:05
User entered 'New'	(b) (4), (b) (6)	17 Feb 2021 15:03:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:50:53
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute on chronic renal failure - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 05:20:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 05:20:29
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE STAGE 3. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:53:01
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE STAGE 3. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'AE term updated to match hospital admission records.' (Site from DM).	Michelle Wiles (b) (4)	05 Apr 2021 17:32:09
Data point term sent to Coder	System	05 Apr 2021 17:32:05
Coding entries removed.	Michelle Wiles (b) (4)	05 Apr 2021 17:31:55
Signature has been broken.	Michelle Wiles (b) (4)	05 Apr 2021 17:31:55
User entered 'Acute renal failure superimposed on chronic kidney disease' reason for change: Per Query Resolution	Michelle Wiles (b) (4)	05 Apr 2021 17:31:55
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE STAGE 3. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:05:27

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	26 Mar 2021 17:49:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 17:49:11
Data point term sent to Coder	System	26 Mar 2021 17:48:22
User closed query 'Per CDM Coding: for term ACUTE RENAL FAILURE SECONDARY TO INTRACTABLE NAUSEA AND VOMITING, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of ACUTE RENAL FAILURE SECONDARY, one of INTRACTABLE NAUSEA and one of VOMITING etc. '(Site from System).	System	26 Mar 2021 17:47:44
Query 'Per CDM Coding: for term ACUTE RENAL FAILURE SECONDARY TO INTRACTABLE NAUSEA AND VOMITING, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of ACUTE RENAL FAILURE SECONDARY, one of INTRACTABLE NAUSEA and one of VOMITING etc. ' answered with 'Separated the AE terms.' (Site from System).	Michelle Wiles (b) (4) (b) (4)	26 Mar 2021 17:47:44
User entered 'ACUTE RENAL FAILURE' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	26 Mar 2021 17:47:39
User opened query 'Per CDM Coding: for term ACUTE RENAL FAILURE SECONDARY TO INTRACTABLE NAUSEA AND VOMITING, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of ACUTE RENAL FAILURE SECONDARY, one of INTRACTABLE NAUSEA and one of VOMITING etc. '(Site from System).	Coder Import (b) (4) (b) (4)	25 Mar 2021 07:40:51
Data point term sent to Coder	System	24 Mar 2021 14:32:09

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Audit	User	Time (GMT)
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate AE records, e.g. ACUTE RENAL FAILURE / INTRACTABLE NAUSEA / VOMITING / ACUTE GASTRITIS etc.' (Site from System).	System	24 Mar 2021 14:31:33
Query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate AE records, e.g. ACUTE RENAL FAILURE / INTRACTABLE NAUSEA / VOMITING / ACUTE GASTRITIS etc.' answered with 'Updated' (Site from System).	Michelle Wiles (b) (4)	24 Mar 2021 14:31:33
User entered 'ACUTE RENAL FAILURE Secondary to INTRACTABLE NAUSEA AND VOMITING' reason for change: Data Entry Error	Michelle Wiles (b) (4)	24 Mar 2021 14:31:27
User entered 'ACUTE RENAL FAILURE FROM INTRACTABLE NAUSEA AND VOMITING' reason for change: Data Entry Error	Michelle Wiles (b) (4)	24 Mar 2021 14:31:09
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate AE records, e.g. ACUTE RENAL FAILURE / INTRACTABLE NAUSEA / VOMITING / ACUTE GASTRITIS etc.' (Site from System).	Coder Import (b) (4)	24 Mar 2021 07:37:29
Data point term sent to Coder	System	23 Mar 2021 14:55:51
DataPoint Un-verified.	Michelle Wiles (b) (4)	23 Mar 2021 14:55:19
Coding entries removed.	Michelle Wiles (b) (4)	23 Mar 2021 14:55:19
User entered 'ACUTE RENAL FAILURE from intractable Nausea and Vomiting and Acute Gastritis' reason for change: Data Entry Error	Michelle Wiles (b) (4)	23 Mar 2021 14:55:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:06:54
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 17:46:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 17:46:02
Data point term sent to Coder	System	17 Feb 2021 17:45:34

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EAB) (1725)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Acute Renal Failure' reason for change: Data Entry Error	Michelle Wiles (b) (4)	17 Feb 2021 17:45:20
Data point term sent to Coder	(b) (4)	
	System	16 Feb 2021 18:20:26
User entered 'Intractable Nausea and Vomiting'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:06:56
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:07:00
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:07:01
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User closed query 'IQVIA Medical query: Please consider whether intractable nausea and vomiting leading to hospitalization meet SAE reporting criteria and update report if appropriate.' (Site from Safety).	(b) (4)	
Query 'IQVIA Medical query: Please consider whether intractable nausea and vomiting leading to hospitalization meet SAE reporting criteria and update report if appropriate.' answered with 'CAUSE OF THE INTRACTABLE NAUSEA AND VOMITING IS DEEMED BY INVESTIGATOR, PER REVIEW OF HOSPITAL ADMISSION NOTES, TO BE DUE TO THE ACUTE RENAL FAILURE AND RESULTANT ELECTROLYTE AND OTHER LAB ABNORMALITIES ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 20:50:17
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 02:04:46
User opened query 'IQVIA Medical query: Please consider whether intractable nausea and vomiting leading to hospitalization meet SAE reporting criteria and update report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:07:07
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 15:52:39
User entered '29 Jan 2021' reason for change: New Information	System	17 Feb 2021 17:45:20
User opened query 'Future date has been entered. Please correct.' (Site from System).	Michelle Wiles (b) (4)	17 Feb 2021 17:45:20
User entered '29 Jun 2021' reason for change: New Information	(b) (4)	16 Feb 2021 18:29:19
User entered '01 Feb 2021'	System	16 Feb 2021 18:29:19
	Michelle Wiles (b) (4)	16 Feb 2021 18:29:19
	(b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:18
User entered empty.	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 18:20:09

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:20
User entered 'No (N)'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:07:31
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	17 Feb 2021 17:45:20
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	16 Feb 2021 18:29:19
User entered '03 Feb 2021'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:07:33
User entered empty.	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

US3482302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 18:20:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:07:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:39
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:42
User entered '0'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:43
User entered '0'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:45
User entered 'I'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:49
User entered '01 Feb 2021'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:51
User entered '03 Feb 2021'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:53
User entered 'No (N)'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:55
User entered empty.	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:07:59
User entered '0'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:08:01
User entered '0'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:08:03
User entered '0'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:08:07
User entered 'Not Related (NOT RELATED)'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:08:08
User entered 'Not Related (NOT RELATED)'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(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)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:51:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Mar 2021 02:06:14
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Mar 2021 02:06:14
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:08:10
User entered 'Dose Delayed (DOSE DELAYED)'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:44:55

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:08:38
User entered '0'	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:51:02
User closed query 'PV Query: Subject was treated with IV fluids, anti-emetics, and PPI. If available, please provide specific treatment medications. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 19:25:02
User closed query 'PV Query: Please provide name of medication that caused gastritis if available. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 19:24:58
Query 'PV Query: Please provide name of medication that caused gastritis if available. ' answered with 'Please refer to below narrative note' (Site from Safety).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:35:31
Query 'PV Query: Subject was treated with IV fluids, anti-emetics, and PPI. If available, please provide specific treatment medications. ' answered with 'Please see con med list, con meds refer to Intractable nausea AE.' (Site from Safety).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:35:11
User opened query 'PV Query: Subject was treated with IV fluids, anti-emetics, and PPI. If available, please provide specific treatment medications. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 11:58:24
User opened query 'PV Query: Please provide name of medication that caused gastritis if available. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 11:58:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:57:50

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Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'As no specific con med was administered for this AE, not recorded.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	22 Mar 2021 16:17:58
User entered '0' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	22 Mar 2021 16:17:55
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:35:39
User entered '1'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:51:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:10:00
(Site from DM).		
User closed query 'PV Query: If available, please provide dates for CTAP, Non-contrast CT of abdomen/pelvis, and HbA1c tests.'	(b) (4), (b) (6)	24 Mar 2021 17:11:17
(Site from Safety).		
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.'	Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:30:01
' answered with 'con procedure removed, added to narrative note.'		
(Site from DM).		
Query 'PV Query: If available, please provide dates for CTAP, Non-contrast CT of abdomen/pelvis, and HbA1c tests.'	Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 14:54:19
' answered with 'On Con Procedure log with date' (Site from Safety).		
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.'	(b) (4), (b) (6)	01 Mar 2021 10:35:33
(Site from DM).		
User opened query 'PV Query: If available, please provide dates for CTAP, Non-contrast CT of abdomen/pelvis, and HbA1c tests.'	(b) (4), (b) (6)	26 Feb 2021 15:51:20
(Site from Safety).		
User entered 'I'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:08:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:08:43
User entered empty.	Michelle Wiles (b) (4)	16 Feb 2021 18:20:09
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:51:09
User closed query 'PV Query: The hospital discharge summary includes diagnoses of newly diagnosed type II diabetes mellitus, hyponatremia, hyperkalemia, hypermagnesemia, and acute gastritis. Please confirm whether any of these events meets the SAE reporting criteria and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 19:25:15
User closed query 'PV Query: If available, please provide potassium, sodium, and glucose levels during hospital admission. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 19:25:11
User closed query 'PV Query: If available, please provide dates for CTAP, Non-contrast CT of abdomen/pelvis, and HbA1c tests' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 19:25:09
User closed query 'PV Query: The records say the subject had "intractable N/V likely due to gastritis" (due to a medication he received during the hospital stay). If correct, can this be additionally recoded with the verbatim for the SAE? ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 19:25:06
Query 'PV Query: The records say the subject had "intractable N/V likely due to gastritis" (due to a medication he received during the hospital stay). If correct, can this be additionally recoded with the verbatim for the SAE? ' answered with 'SAE recorded from admission records. Will not change.' (Site from Safety).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:42:28
Query 'PV Query: If available, please provide dates for CTAP, Non-contrast CT of abdomen/pelvis, and HbA1c tests' answered with 'Please see AE for DM2 for HbA1c. All other dates in narrative note.' (Site from Safety).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:42:04
Query 'PV Query: The hospital discharge summary includes diagnoses of newly diagnosed type II diabetes mellitus, hyponatremia, hyperkalemia, hypermagnesemia, and acute gastritis. Please confirm whether any of these events meets the SAE reporting criteria and update report if appropriate. ' answered with 'Please see other AEs. ' (Site from Safety).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:34:34

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: If available, please provide potassium, sodium, and glucose levels during hospital admission. ' answered with 'See narrative NOTE' (Site from Safety).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:33:05
User opened query 'PV Query: The hospital discharge summary includes diagnoses of newly diagnosed type II diabetes mellitus, hyponatremia, hyperkalemia, hypermagnesemia, and acute gastritis. Please confirm whether any of these events meets the SAE reporting criteria and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 11:58:55
User opened query 'PV Query: If available, please provide potassium, sodium, and glucose levels during hospital admission. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 11:58:38
User opened query 'PV Query: If available, please provide dates for CTAP, Non-contrast CT of abdomen/pelvis, and HbA1c tests' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 11:58:14
User opened query 'PV Query: The records say the subject had "intractable N/V likely due to gastritis" (due to a medication he received during the hospital stay). If correct, can this be additionally recoded with the verbatim for the SAE? ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 11:57:26
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:34:27
User closed query 'IQVIA Medical query: The hospital discharge summary includes diagnoses of newly diagnosed type II diabetes mellitus, hyponatremia, hyperkalemia, hypermagnesemia, and acute gastritis. Please confirm whether any of these events meets the SAE reporting criteria and update report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 17:11:40
User closed query 'PV Query: If available, please provide potassium, sodium, and glucose levels during hospital admission.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 17:11:35
User closed query 'PV Query: Please provide name of medication that caused gastritis if available.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 17:11:31
User closed query 'PV Query: Subject was treated with IV fluids, anti-emetics, and PPI. If available, please provide specific treatment medications' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 17:11:27

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The records say the subject had “intractable N/V likely due to gastritis” (due to a medication he received during the hospital stay). If correct, can this be additionally recoded with the verbatim for the SAE?' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 17:11:23
User closed query 'Per DM CLR: Narrative = HYPERKALEMIA, HYPONATREMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:55:37
User closed query 'Per DM CLR: Narrative = NEW MEDICATION HE WAS PRESCRIBED IN THE HOSPITAL. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:55:13

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS ADMITTED TO THE EMERGENCY DEPARTMENT ON 2/1/2021 WITH DECREASED APPETITE AND NAUSEA. HE STATES THAT HE WAS TAKING ASCORBIC ACID THAT WAS PRESCRIBED FROM HIS PREVIOUS HOSPITALIZATION THAT WAS MAKING HIM NAUSEATED. WHILE IN THE EMERGENCY DEPARTMENT, THE SUBJECT UNDERWENT LABS. BLOOD GLUCOSE WAS FOUND TO BE ELEVATED (359) WITH AN HGBA1C OF 8.5 IN ADDITION TO AN ELEVATED MAGNESIUM (2.7) AND AN ELEVATED POTASSIUM (5.2). He also had hyponatremia (Na 131). HE WAS STARTED ON IV NS VIA BOLUS AND INSULIN, WHICH IS DOCUMENTED IN HIS CON MEDS. A CT OF THE ABDOMEN AND PELVIS DONE ON 2/1/2021 SHOWED NO ACUTE ABNORMALITIES IN HIS ABDOMEN. HE WAS STARTED ON OMEPRAZOLE FOR HIS ACUTE GI SYMPTOMS AND SODIUM CHLORIDE TABLETS TO TREAT HIS HYPONATREMIA. NO DOCUMENTED ANTI-EMETICS WERE ADMINISTERED PER HIS MEDICAL RECORDS. ALL MEDICATIONS FROM HIS HOSPITALIZATION ARE INCLUDED IN HIS CON MED LOG AND HIS ADMITTING DIAGNOSES ARE RECORDED AS SEPARATE AES.' reason for change: New Information	Michelle Wiles (b) (4)	23 Mar 2021 16:35:11
Query 'PV Query: If available, please provide potassium, sodium, and glucose levels during hospital admission.' answered with 'Added to new narrative note' (Site from Safety).	Michelle Wiles (b) (4)	23 Mar 2021 16:30:22
Query 'PV Query: Subject was treated with IV fluids, anti-emetics, and PPI. If available, please provide specific treatment medications' answered with 'Added to new narrative note' (Site from Safety).	Michelle Wiles (b) (4)	23 Mar 2021 16:30:18

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject was admitted to the emergency department on 2/1/2021 with decreased appetite and nausea. He states that he was taking ascorbic acid that was prescribed from his previous hospitalization that was making him nauseated. While in the emergency department, the subject underwent labs. Blood glucose was found to be elevated (359) with an HgbA1C of 8.5 in addition to an elevated magnesium (2.7) and an elevated potassium (5.2). He was started on IV NS via bolus and insulin, which is documented in his con meds. A CT of the abdomen and pelvis done on 2/1/2021 showed no acute abnormalities in his abdomen. He was started on omeprazole for his acute GI symptoms and sodium chloride tablets to treat his hyponatremia. No documented anti-emetics were administered per his medical records. All medications from his hospitalization are included in his con med log and his admitting diagnoses are recorded as separate AEs.' reason for change: New Information	Michelle Wiles (b) (4)	23 Mar 2021 15:57:43
User entered 'SUBJECT READMITTED TO THE HOSPITAL FOLLOWING HOSPITALIZATION FOR COVID 19. RECEIVED RECORDS FOR SUBSEQUENT HOSPITALIZATION ON 15FEB2021. ADMITTED FOR INTRACTABLE N/V WHICH SUBJECT REPORTED AT DAY 28 VISIT WAS RELATED TO A NEW MEDICATION HE WAS PRESCRIBED IN THE HOSPITAL (ASCORBIC ACID), acute on CKD, HYPERKALEMIA, HYPONATREMIA, AND HYPERGLYCEMIA that led to newly diagnosed diabetes.' reason for change: New Information	Michelle Wiles (b) (4)	23 Mar 2021 15:43:56
Query 'PV Query: Please provide name of medication that caused gastritis if available.' answered with 'name added to narrative note.' (Site from Safety).	Michelle Wiles (b) (4)	23 Mar 2021 15:17:55
Query 'Per DM CLR: Narrative = HYPERKALEMIA, HYPONATREMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Recorded as separate AE' (Site from DM).	Michelle Wiles (b) (4)	23 Mar 2021 15:17:27

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[Narrative](#)

Audit	User	Time (GMT)
Query 'IQVIA Medical query: The hospital discharge summary includes diagnoses of newly diagnosed type II diabetes mellitus, hyponatremia, hyperkalemia, hypermagnesemia, and acute gastritis. Please confirm whether any of these events meets the SAE reporting criteria and update report if appropriate.' answered with 'Separate AE forms for each diagnosis added. Awaiting guidance from study monitor on whether they meet the SAE reporting criteria.' (Site from Safety).	Michelle Wiles (b) (4)	23 Mar 2021 15:17:18
Query 'Per DM CLR: Narrative = NEW MEDICATION HE WAS PRESCRIBED IN THE HOSPITAL. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated name of medication in narrative note, on con med list.' (Site from DM).	Michelle Wiles (b) (4)	23 Mar 2021 15:15:01
User entered 'SUBJECT READMITTED TO THE HOSPITAL FOLLOWING HOSPITALIZATION FOR COVID 19. RECEIVED RECORDS FOR SUBSEQUENT HOSPITALIZATION ON 15FEB2021. ADMITTED FOR INTRACTABLE N/V WHICH SUBJECT REPORTED AT DAY 28 VISIT WAS RELATED TO A NEW MEDICATION HE WAS PRESCRIBED IN THE HOSPITAL (ASCORBIC ACID), CKD, HYPERKALEMIA, HYPONATREMIA, AND HYPERGLYCEMIA.' reason for change: Data Entry Error	Michelle Wiles (b) (4)	23 Mar 2021 15:14:43
Query 'PV Query: The records say the subject had "intractable N/V likely due to gastritis" (due to a medication he received during the hospital stay). If correct, can this be additionally recoded with the verbatim for the SAE?' answered with 'SAE updated.' (Site from Safety).	Michelle Wiles (b) (4)	23 Mar 2021 14:55:39
User closed query 'PV Query: Please update action taken with study drug from dose delayed to not applicable as subject received both scheduled doses of study drug.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 20:50:28
Query 'PV Query: Please update action taken with study drug from dose delayed to not applicable as subject received both scheduled doses of study drug.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	20 Mar 2021 02:06:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = HYPERKALEMIA, HYPONATREMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:35:28
User opened query 'Per DM CLR: Narrative = NEW MEDICATION HE WAS PRESCRIBED IN THE HOSPITAL. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:35:03
User opened query 'QVIA Medical query: The hospital discharge summary includes diagnoses of newly diagnosed type II diabetes mellitus, hyponatremia, hyperkalemia, hypermagnesemia, and acute gastritis. Please confirm whether any of these events meets the SAE reporting criteria and update report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:00:04
User opened query 'PV Query: If available, please provide potassium, sodium, and glucose levels during hospital admission.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:51:53
User opened query 'PV Query: Please provide name of medication that caused gastritis if available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:51:36
User opened query 'PV Query: Subject was treated with IV fluids, anti-emetics, and PPI. If available, please provide specific treatment medications' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:50:58
User opened query 'PV Query: Please update action taken with study drug from dose delayed to not applicable as subject received both scheduled doses of study drug.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:50:12
User opened query 'PV Query: The records say the subject had "intractable N/V likely due to gastritis" (due to a medication he received during the hospital stay). If correct, can this be additionally recoded with the verbatim for the SAE?' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:49:10

US3482302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject readmitted to the hospital following hospitalization for COVID 19. Received records for subsequent hospitalization on 15Feb2021. Admitted for intractable N/V which subject reported at Day 28 visit was related to a new medication he was prescribed in the hospital, CKD, hyperkalemia, hyponatremia, and hyperglycemia.'	Michelle Wiles (b) (4) (b) (4)	16 Feb 2021 18:20:09

US3482302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 18:20:09

US3482302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 18:20:09

US3482302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Feb 2021 18:20:09

US3482302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Feb 2021 23:07:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 23:07:01
Data point term sent to Coder	System	17 Feb 2021 18:23:53
User entered 'DIABETES TYPE II, new onset' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 18:23:23
Data point term sent to Coder	System	17 Feb 2021 18:10:27
User entered 'Diabetes Type II Hyperglycemia'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

US3482302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

US3482302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '01 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:33
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Grade 3/Severe (Grade 3/Severe)'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:40
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:16:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:16:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:16:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:16:53
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:16:55
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:16:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:17:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:17:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:17:04
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:17:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

US3482302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:17:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'I'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:17:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

US3482302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:17:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:17:40
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:17:55
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	05 Apr 2021 17:41:21
User entered 'BLOOD GLUCOSE RECORDINGS FROM 290-359, HGB A1C 8.5 drawn on 2/1/2021.' reason for change: New Information	(b) (4) Michelle Wiles (b) (4)	05 Apr 2021 17:41:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'BLOOD GLUCOSE RECORDINGS FROM 290-359, Hgb A1C 8.5.' reason for change: New Information	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 15:30:41
User entered 'Blood glucose recordings from 290-359' reason for change: Data Entry Error	Michelle Wiles (b) (4)	23 Mar 2021 15:22:35
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 18:10:25

US3482302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 18:10:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 16:49:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 16:49:38
Data point term sent to Coder	System	23 Mar 2021 16:33:57
User entered 'Hyponatremia'	Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:12
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:14
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '01 Feb 2021'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4)	
	Michelle Wiles (b) (4)	23 Mar 2021 16:33:24
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
User entered empty.	System	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '03 Feb 2021'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
User entered empty.	System	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:40
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:52
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:18:59
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:19:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:19:04
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'l'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:19:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:19:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:19:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:19:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Subject found to have sodium level of 131 on admission labs, treated with sodium chloride tablet, IV fluids.'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
User entered '0'	System	23 Mar 2021 16:33:24

US3482302

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10
User entered 'I'	System	23 Mar 2021 16:33:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:19:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hyperkalaemia, LLT: Hyperkalemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 16:38:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 16:38:39
Data point term sent to Coder	System	23 Mar 2021 16:38:06
User entered 'Hyperkalemia'	Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:20:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:20:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '01 Feb 2021'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:20:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
User entered empty.	System	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:20:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '02 Feb 2021'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
User entered empty.	System	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:33
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:40
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4)	
	Michelle Wiles (b) (4)	23 Mar 2021 16:37:35
	(b) (4)	

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Folder: Adverse Events

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

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)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:21:59
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'l'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:04
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:12
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
User entered '0'	System	23 Mar 2021 16:37:35

US3482302

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14
User entered 'I'	System	23 Mar 2021 16:37:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:14

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Folder: Adverse Events

Form: Adverse Events (6)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Hypermagnesaemia, LLT: Hypermagnesemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 16:39:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 16:39:38
Data point term sent to Coder	System	23 Mar 2021 16:39:07
User entered 'Hypermagnesemia'	Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:24
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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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)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '01 Feb 2021'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:22:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
User entered empty.	System	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
User closed query 'Source document not marked. Please verify and update source or EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 18:57:11
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:57:10
Query 'Source document not marked. Please verify and update source or EDC as needed.' answered with 'source updated' (Site from CRA).	Mari Hart (b) (4)	26 Apr 2021 18:02:54
User opened query 'Source document not marked. Please verify and update source or EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:23:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	Michelle Wiles (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:25:59
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '03 Feb 2021'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
User entered empty.	System	23 Mar 2021 16:38:29

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:12
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:14
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4)	
	Michelle Wiles (b) (4)	23 Mar 2021 16:38:29
	(b) (4)	

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Folder: Adverse Events

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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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)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

US3482302

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:33
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'l'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

US3482302

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

US3482302

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:39
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

US3482302

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

US3482302

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

US3482302

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:38:29

US3482302

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
User entered '0'	System	23 Mar 2021 16:38:29

US3482302

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18
User entered 'I'	System	23 Mar 2021 16:38:29

US3482302

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:41:18

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:35
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:25:42
User entered 'USA-US106-2021-mRNA-1273-P301000011'	(b) (4), (b) (6)	29 Mar 2021 15:25:36

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 17:51:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 17:51:27
Data point term sent to Coder	System	26 Mar 2021 17:50:25
User entered 'Intractable Nausea'	Michelle Wiles (b) (4)	26 Mar 2021 17:49:54
	(b) (4)	

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:39
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '29 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Mar 2021 17:50:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 17:50:29
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	26 Mar 2021 17:50:29
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 17:49:54
User entered empty.	Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '03 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:53
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:52:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
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	26 Mar 2021 17:50:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	26 Mar 2021 17:50:16
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 17:49:54
User entered empty.	Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'I'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '01 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '03 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'I'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:33
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:40
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:42
User closed query 'IQVIA Medical query: The hospital discharge summary includes diagnoses of newly diagnosed type II diabetes mellitus, hyponatremia, hyperkalemia, hypermagnesemia, and acute gastritis. Please confirm whether any of these events meets the SAE reporting criteria and update report if appropriate.	(b) (4), (b) (6)	06 Apr 2021 19:26:38
' (Site from Safety). User closed query 'PV Query: The records say the subject had "intractable N/V likely due to gastritis" (due to a medication he received during the hospital stay). If correct, can this be additionally recoded with the verbatim for the SAE? ' (Site from Safety). Query 'PV Query: The records say the subject had "intractable N/V likely due to gastritis" (due to a medication he received during the hospital stay). If correct, can this be additionally recoded with the verbatim for the SAE? ' answered with 'Per previous query, SAE term updated per hospital source records.' (Site from Safety). Query 'IQVIA Medical query: The hospital discharge summary includes diagnoses of newly diagnosed type II diabetes mellitus, hyponatremia, hyperkalemia, hypermagnesemia, and acute gastritis. Please confirm whether any of these events meets the SAE reporting criteria and update report if appropriate.	(b) (4), (b) (6) Michelle Wiles (b) (4) (b) (4) Michelle Wiles (b) (4) (b) (4)	06 Apr 2021 19:26:33 05 Apr 2021 17:36:41 05 Apr 2021 17:36:24
' answered with 'Please see other AE, does not meet SAE criteria.' (Site from Safety). User opened query 'IQVIA Medical query: The hospital discharge summary includes diagnoses of newly diagnosed type II diabetes mellitus, hyponatremia, hyperkalemia, hypermagnesemia, and acute gastritis. Please confirm whether any of these events meets the SAE reporting criteria and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:07:08

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The records say the subject had “intractable N/V likely due to gastritis” (due to a medication he received during the hospital stay). If correct, can this be additionally recoded with the verbatim for the SAE? ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) (b) (4)	05 Apr 2021 13:07:01
	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:34:27
User entered 'Related to SAE for acute renal failure, split into two separate diagnoses per query resolution.'	Michelle Wiles (b) (4) (b) (4)	26 Mar 2021 17:49:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 17:50:16

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 17:49:54

US3482302

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:44:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 17:49:54

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:44:55

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:54:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 08:24:34
Query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'subject selected "yes" by mistake. they did not take any pain medication.' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	18 Mar 2021 13:51:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:59:28
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 02:57:14
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:26:51

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 16:29:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:29:25
Data point term sent to Coder	System	19 Oct 2020 16:28:20
User entered 'Amlodipine'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:27:24

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Hypertension'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:27:24

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered '10'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'mg (mg)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'once daily (QD)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Oral (ORAL)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'un UNK 2014'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered '0'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:24
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:27:24

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:27:24

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:27:24

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 16:29:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:29:25
Data point term sent to Coder	System	19 Oct 2020 16:28:21
User entered 'Metoprolol'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:27:55

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'hypertension'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:27:55

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered '25'	Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'mg (mg)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:27:55

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'twice daily (BID)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:27:55

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Oral (ORAL)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:27:55

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'un UNK 2014'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:27:55
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 16:27:55

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:27:55

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:27:55

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 16:30:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:30:28
Data point term sent to Coder	System	19 Oct 2020 16:29:22
User entered 'Latanoprost 0.005%'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:28:42

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:28:42
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Glaucoma'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:28:42

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'I'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:28:42

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Other (OTHER)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:28:42

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'drop/eye'	Sarah Bechnak (b) (4)	19 Oct 2020 16:28:42
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'once daily (QD)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:28:42
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:28:42
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:24
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'REVIEWED, ROUTE IS CORRECT' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 19:28:35
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:25:03
User entered 'Intraocular (INTRAOCULAR)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:28:42

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:28:42
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'un UNK 2017'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:28:42
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:28:42
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:28:42

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:28:42
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:28:42
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:28:42

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:28:42

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:28:42

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: DORZOLAMIDE;TIMOLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Oct 2020 13:39:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:39:39
Data point term sent to Coder	System	19 Oct 2020 16:31:24
User entered 'Dorzalomid 22.3 mg/ Timolol 6.8 mg/ml'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:30:31

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:30:31
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Glaucoma'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:30:31

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '2'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:30:31

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:30:31
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'drops/eye'	Sarah Bechnak (b) (4)	19 Oct 2020 16:30:31
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'once daily (QD)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:30:31
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:30:31
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:29
Query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' answered with 'REVIEWED, ROUTE IS CORRECT' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	01 Dec 2020 19:28:51
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:25:35
User entered 'Intraocular (INTRAOCULAR)'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:30:31

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:30:31
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'un UNK 2017'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:30:31
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:30:31

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:30:31

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:30:31
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:30:31
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:30:31

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:30:31

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:30:31

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 23:31:27
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 Oct 2020 23:31:27
Data point term sent to Coder	System	19 Oct 2020 16:32:26
User entered 'diclofenac'	Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:32:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'arthritis in knee'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:32:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '1'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'application'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:32:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'as needed (PRN)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:32:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Topical (TOPICAL)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Oct 2020 16:32:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'un UNK 2016'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered '0'	Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	19 Oct 2020 16:32:19
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:32:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:32:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:32:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:44:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:07:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:07:02
Data point term sent to Coder	System	17 Feb 2021 15:03:17
User entered 'Zinc Sulfate'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:44:18
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:44:19
User entered 'COVID 19'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:44:21
User entered '220'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:44:23
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:44:25
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:44:27
User entered 'once daily (QD)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:44:29
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:44:31
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:45:14
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:45:17
User entered '22 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:45:19
User entered '0'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:45:20
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:45:22
User entered '30 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:45:23
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User entered '1'	System	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User entered '1'	System	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:39:31
User entered '804 (804)'	System	17 Feb 2021 15:03:11

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Feb 2021 08:15:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:15:48
Data point term sent to Coder	System	17 Feb 2021 15:10:21
User entered 'Famotidine'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Peptic Ulcer Disease Prophylaxis'	Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '20'	Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'mg (mg)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'once daily (QD)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Oral (ORAL)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '22 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '24 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User entered '1'	System	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User entered '1'	System	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:31:48
User entered '804 (804)'	System	17 Feb 2021 15:09:22

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:12:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:12:49
Data point term sent to Coder	System	17 Feb 2021 15:13:23
User entered 'Ascorbic Acid'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:25
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:27
User entered 'COVID 19'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:29
User entered '500'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:33
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:34
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:37
User entered 'once daily (QD)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:39
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:42
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:43
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:47
User entered '22 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:49
User entered '0'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:50
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:52
User entered '30 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:53
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User entered '1'	System	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User entered '1'	System	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:15
User entered '804 (804)'	System	17 Feb 2021 15:13:07

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DEXMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:58:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:58:56
Data point term sent to Coder	System	17 Feb 2021 15:15:26
User entered 'Dexamethasone'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:07
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:08
User entered 'COVID 19'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:13
User entered '6'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:15
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:16
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:20
User entered 'once (ONCE)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:25
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:30
User entered 'Intravenous (INTRAVENOUS)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:31
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:33
User entered '21 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:35
User entered '0'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:37
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:40
User entered '21 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:43
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User entered empty.	System	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User entered empty.	System	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:07
User entered empty.	System	17 Feb 2021 15:15:19

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:55
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DEXMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:59:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:59:56
Data point term sent to Coder	System	17 Feb 2021 15:16:27
User entered 'Dexamethasone'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:57
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:50:59
User entered 'COVID 19'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:05
User entered '6'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:02
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:16
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:19
User entered 'once daily (QD)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:32
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:34
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:36
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:51
User entered '22 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:53
User entered '0'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:55
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:51:57
User entered '01 Feb 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:52:00
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User entered '1'	System	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User entered '1'	System	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:16:51
User entered '804 (804)'	System	17 Feb 2021 15:15:58

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:52:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 15:19:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 15:19:02
Data point term sent to Coder	System	17 Feb 2021 15:18:29
User entered 'Acetaminophen'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:52:40
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:52:46
User entered 'Fever'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:52:48
User entered '650'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:52:52
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:28
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:30
User entered 'as needed (PRN)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:32
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:35
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:40
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:42
User entered '21 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:45
User entered '0'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:46
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:48
User entered '25 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:50
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User entered empty.	System	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User entered empty.	System	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:35:58
User entered empty.	System	17 Feb 2021 15:17:41

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:22:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:22:46
Data point term sent to Coder	System	17 Feb 2021 15:19:29
User entered 'Azythromycin'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:11
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:15
User entered 'COVID 19'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:20
User entered '500'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:22
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:24
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:26
User entered 'once daily (QD)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:28
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:30
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:32
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:34
User entered '21 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:46
User entered '0'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:48
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:50
User entered '25 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:54:52
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User entered '1'	System	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User entered '1'	System	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:39:01
User entered '804 (804)'	System	17 Feb 2021 15:19:25

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 08:04:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:04:49
Data point term sent to Coder	System	17 Feb 2021 15:22:34
User entered 'Enoxaparin'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'VTE prophylaxis'	Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '40'	Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'mg (mg)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'once daily (QD)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Subcutaneous (SUBCUTANEOUS)'	Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '22 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '25 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	Michelle Wiles (b) (4)	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User entered '1'	System	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User entered '1'	System	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:58
User entered '804 (804)'	System	17 Feb 2021 15:22:13

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:55:09
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: REMDESIVIR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 15:25:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 15:25:00
Data point term sent to Coder	System	17 Feb 2021 15:24:35
User entered 'Remdesivir'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:04
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:06
User entered 'COVID 19'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:08
User entered '100'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:12
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:15
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:17
User entered 'once daily (QD)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:21
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:24
User entered 'Intravenous (INTRAVENOUS)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:26
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:29
User entered '22 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:30
User entered '0'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:32
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:34
User entered '25 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:35
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User entered '1'	System	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User entered '1'	System	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:36
User entered '804 (804)'	System	17 Feb 2021 15:23:56

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:57:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:57:57
Data point term sent to Coder	System	17 Feb 2021 15:25:36
User entered 'Ceftriaxone'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:49
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:50
User entered 'COVID 19 related pneumonia'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:54
User entered '2'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:55
User entered 'g (g)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:57
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:57:59
User entered 'once daily (QD)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:58:02
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:58:07
User entered 'Intravenous (INTRAVENOUS)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:58:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:58:11
User entered '21 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:58:15
User entered '0'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:58:16
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:58:19
User entered '24 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:58:21
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User entered '1'	System	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User entered '1'	System	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:04:08
User entered '804 (804)'	System	17 Feb 2021 15:25:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Feb 2021 14:22:49
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:22:49
Data point term sent to Coder	System	17 Feb 2021 15:27:41
User entered 'Metformin'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:26:46

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	17 Feb 2021 15:26:46
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Hyperglycemia from newly diagnosed Diabetes Type II'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:26:46

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '500'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:26:46

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'mg (mg)'	Michelle Wiles (b) (4)	17 Feb 2021 15:26:46
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:26:46
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'twice daily (BID)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:26:46
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:26:46

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Oral (ORAL)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:26:46

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:26:46
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '03 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:26:46
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 15:26:46
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	17 Feb 2021 15:26:46
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	17 Feb 2021 15:26:46
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:26:46

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Feb 2021 15:26:46

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 15:26:46

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Feb 2021 15:26:46

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 08:04:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:04:49
Data point term sent to Coder	System	17 Feb 2021 15:27:40
User entered 'Enoxaparin'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'VTE Prophylaxis'	Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '40'	Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'mg (mg)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'once daily (QD)'	Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '01 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '03 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User entered '1'	System	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User entered '1'	System	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:22:11
User entered '804 (804)'	System	17 Feb 2021 15:27:34

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:46:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:46:35
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:34:27
Data point term sent to Coder	System	23 Mar 2021 15:24:33
Coding entries removed.	Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 15:24:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:45:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:45:48
Data point term sent to Coder	System	17 Feb 2021 15:28:41
User entered 'Humalog Insulin'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'HYPERGLYCEMIA FROM NEWLY DIAGNOSED DIABETES TYPE II' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 15:24:03
User entered 'Hyperglycemia'	Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '2'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Other (OTHER)'	Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Units'	Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'three times daily (TID)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '01 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '03 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User entered '3'	System	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User entered '1'	System	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:50
User entered '804 (804)'	System	17 Feb 2021 15:28:26

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Feb 2021 10:55:02
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 Feb 2021 10:55:02
Data point term sent to Coder	System	17 Feb 2021 15:29:42
User entered 'Omeprazole'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	17 Feb 2021 15:29:00
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'GERD Prophylaxis'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '40'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'mg (mg)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'once daily (QD)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Oral (ORAL)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered '04 Feb 2021'	Michelle Wiles (b) (4)	17 Feb 2021 15:29:00
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
	(b) (4)	
User entered '0'	Michelle Wiles (b) (4)	17 Feb 2021 15:29:00
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Feb 2021 15:29:00

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: SODIUM, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:48:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:48:17
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:34:27
Data point term sent to Coder	System	23 Mar 2021 16:03:58
User entered 'Sodium Chloride'	Michelle Wiles (b) (4) (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Hyponatremia'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '1000'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'mg (mg)'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
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	23 Mar 2021 16:03:25
User entered 'three times daily (TID)' reason for change: Data Entry Error	System	23 Mar 2021 16:03:25
User opened query 'Data is required. Please complete.' (Site from System).	Michelle Wiles (b) (4)	23 Mar 2021 16:03:25
User entered empty.	(b) (4)	
	System	23 Mar 2021 16:03:16
	Michelle Wiles (b) (4)	23 Mar 2021 16:03:16
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
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	23 Mar 2021 16:03:25
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	23 Mar 2021 16:03:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Mar 2021 16:03:16
	Michelle Wiles (b) (4)	23 Mar 2021 16:03:16
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered empty.	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '02 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '0'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '03 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User entered '3'	System	23 Mar 2021 16:03:25
User entered empty.	System	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User entered '1'	System	23 Mar 2021 16:03:25
User entered empty.	System	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:03
User entered '804 (804)'	System	23 Mar 2021 16:03:25
User entered empty.	System	23 Mar 2021 16:03:16

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: KETOROLAC TROMETHAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Apr 2021 08:49:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:49:51
Data point term sent to Coder	System	13 Apr 2021 19:13:29
User entered 'ketorolac tromethamine'	Michelle Wiles (b) (4) (b) (4)	13 Apr 2021 19:12:48

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	14 Apr 2021 13:58:25
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	13 Apr 2021 19:12:48

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'Left Eye Cataract Removal'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:12:48

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered '1'	Michelle Wiles (b) (4)	13 Apr 2021 19:12:48
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'Other (OTHER)'	Michelle Wiles (b) (4)	13 Apr 2021 19:12:48
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'gtt'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:12:48
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'three times daily (TID)'	Michelle Wiles (b) (4)	13 Apr 2021 19:12:48
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered empty.	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:12:48
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'Other (OTHER)'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:12:48

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'Otic'	Michelle Wiles (b) (4)	13 Apr 2021 19:12:48
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered '29 Mar 2021'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:12:48
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered '0'	Michelle Wiles (b) (4)	13 Apr 2021 19:12:48
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:12:48

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered empty.	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:12:48
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:12:48

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 19:12:48

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 19:12:48

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 19:12:48

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: DIFLUPREDNATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 10:08:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:08:46
Data point term sent to Coder	System	13 Apr 2021 19:14:32
User entered 'Difluprednate'	Michelle Wiles (b) (4) (b) (4)	13 Apr 2021 19:13:53

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'Left Eye Cataract Removal'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:13:53

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered '1'	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'Other (OTHER)'	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'gtt'	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'three times daily (TID)'	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'Other (OTHER)'	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'Otic'	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered '29 Mar 2021'	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered '0'	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:13:53

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:13:53
	(b) (4)	

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:13:53

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 19:13:53

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 19:13:53

US3482302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 19:13:53

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:44:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:54:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 15:12:56
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 15:12:49
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:12:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	17 Feb 2021 15:30:03
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 16:50:14

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:44:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:14
User entered '22 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:32:21

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:44:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:16
User entered 'Lung Perfusion Scan'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:32:21

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:17
User entered 'Diagnostic (DIAGNOSTIC)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:32:21

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:44:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:19
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:32:21

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:44:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:28
User entered '21 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:38:00

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:44:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:30
User entered 'X-ray Chest'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:38:00

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:32
User entered 'Diagnostic (DIAGNOSTIC)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:38:00

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:44:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:33
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:38:00

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:44:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:42
User entered '22 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:40:38

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:44:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:45
User entered 'Convalescent Plasma Infusion'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:40:38

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:46
User entered 'Adverse Event (AE)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:40:38

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:44:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:49
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:40:38

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:44:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:13:59
User entered '21 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:41:45

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:44:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:14:01
User entered 'Supplemental Oxygen'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:41:45

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:14:02
User entered 'Adverse Event (AE)'	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:41:45

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:44:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:14:04
User entered empty.	Michelle Wiles (b) (4) (b) (4)	17 Feb 2021 15:41:45

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:44:55

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered '29 Mar 2021'	Michelle Wiles (b) (4)	13 Apr 2021 19:08:08
	(b) (4)	

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:44:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
User entered 'Left Eye Cataract Removal'	(b) (4) Michelle Wiles (b) (4)	13 Apr 2021 19:08:08

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:44:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered 'Medical History (MH)'	Michelle Wiles (b) (4)	13 Apr 2021 19:08:08
	(b) (4)	

US3482302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:44:55

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:51
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	13 Apr 2021 19:08:08
	(b) (4)	

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'USA-US106-2021-MRNA-1273-P301000008'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Easton'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Beshears'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '500 Irvin Court'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Decatur'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'GA'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '30030'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'US'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 16:33:37
User entered '6'	System	05 Mar 2021 18:44:15
User entered '5'	System	18 Feb 2021 17:12:14
User entered '4'	System	17 Feb 2021 14:36:47
User entered '3'	System	16 Feb 2021 15:02:20
User entered '2'	System	29 Jan 2021 16:01:47
User entered '1'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'USA-US106-2021-MRNA-1273-P301000008'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Easton'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Beshears'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '500 Irvin Court'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Decatur'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'GA'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '30030'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'US'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 16:33:37
User entered '6'	System	05 Mar 2021 18:44:15
User entered '5'	System	18 Feb 2021 17:12:14
User entered '4'	System	17 Feb 2021 14:36:47
User entered '3'	System	16 Feb 2021 15:02:20
User entered '2'	System	29 Jan 2021 16:01:47
User entered '1'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:16
User entered '29/Jan/2021 10:41'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'USA-US106-2021-MRNA-1273-P301000008'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Easton'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Beshears'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '500 Irvin Court'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Decatur'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'GA'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '30030'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'US'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 16:33:37
User entered '6'	System	05 Mar 2021 18:44:15
User entered '5'	System	18 Feb 2021 17:12:14
User entered '4'	System	17 Feb 2021 14:36:47
User entered '3'	System	16 Feb 2021 15:02:20
User entered '2'	System	29 Jan 2021 16:01:47
User entered '1'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:16
User entered '29/Jan/2021 11:01'	System	29 Jan 2021 16:01:47

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 16:01:47

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'USA-US106-2021-MRNA-1273-P301000008'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Easton'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Beshears'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '500 Irvin Court'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Decatur'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'GA'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '30030'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'US'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 16:33:37
User entered '6'	System	05 Mar 2021 18:44:15
User entered '5'	System	18 Feb 2021 17:12:14
User entered '4'	System	17 Feb 2021 14:36:47
User entered '3'	System	16 Feb 2021 15:02:20
User entered '2'	System	29 Jan 2021 16:01:47
User entered '1'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '16/Feb/2021 10:02'	(b) (4) System	16 Feb 2021 15:02:20

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:36:30
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 15:02:20

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'USA-US106-2021-MRNA-1273-P301000008'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Easton'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Beshears'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '500 Irvin Court'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Decatur'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'GA'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '30030'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'US'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 16:33:37
User entered '6'	System	05 Mar 2021 18:44:15
User entered '5'	System	18 Feb 2021 17:12:14
User entered '4'	System	17 Feb 2021 14:36:47
User entered '3'	System	16 Feb 2021 15:02:20
User entered '2'	System	29 Jan 2021 16:01:47
User entered '1'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '17/Feb/2021 09:36'	(b) (4) System	17 Feb 2021 14:36:47

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 17:11:44
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 14:36:47

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'USA-US106-2021-MRNA-1273-P301000008'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Easton'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Beshears'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '500 Irvin Court'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Decatur'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'GA'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '30030'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'US'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 16:33:37
User entered '6'	System	05 Mar 2021 18:44:15
User entered '5'	System	18 Feb 2021 17:12:14
User entered '4'	System	17 Feb 2021 14:36:47
User entered '3'	System	16 Feb 2021 15:02:20
User entered '2'	System	29 Jan 2021 16:01:47
User entered '1'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '18/Feb/2021 12:12'	(b) (4) System	18 Feb 2021 17:12:14

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 18:43:52
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 17:12:14

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'USA-US106-2021-MRNA-1273-P301000008'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Easton'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Beshears'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '500 Irvin Court'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Decatur'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'GA'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '30030'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'US'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 16:33:37
User entered '6'	System	05 Mar 2021 18:44:15
User entered '5'	System	18 Feb 2021 17:12:14
User entered '4'	System	17 Feb 2021 14:36:47
User entered '3'	System	16 Feb 2021 15:02:20
User entered '2'	System	29 Jan 2021 16:01:47
User entered '1'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '05/Mar/2021 13:44'	(b) (4) System	05 Mar 2021 18:44:15

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:44:15

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'USA-US106-2021-MRNA-1273-P301000008'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Yes (Y)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'No (N)'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Easton'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'Beshears'	System	29 Jan 2021 15:40:39

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '500 Irvin Court'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'Decatur'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'GA'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '30030'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:20
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:48:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 16:01:52
User entered 'US'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 16:33:37
User entered '6'	System	05 Mar 2021 18:44:15
User entered '5'	System	18 Feb 2021 17:12:14
User entered '4'	System	17 Feb 2021 14:36:47
User entered '3'	System	16 Feb 2021 15:02:20
User entered '2'	System	29 Jan 2021 16:01:47
User entered '1'	System	29 Jan 2021 15:41:10

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '29/Mar/2021 12:33'	(b) (4) System	29 Mar 2021 16:33:37

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:33:37

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered		
'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
User entered '17/Feb/2021 10:10'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
User entered '18/Feb/2021 11:47'	System	18 Feb 2021 16:47:14

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:11:59
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 16:47:14

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '22/Mar/2021 06:32'	(b) (4) System	22 Mar 2021 13:32:09

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:11:59
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:32:09
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 13:31:59

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered		
'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '23/Mar/2021 08:17'	(b) (4) System	23 Mar 2021 12:17:51

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:11:59
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 12:17:51

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '23/Mar/2021 09:36'	(b) (4) System	23 Mar 2021 13:36:43

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:11:59
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 13:36:43

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered		
'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '24/Mar/2021 12:12'	(b) (4) System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered		
'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '25/Mar/2021 11:09'	(b) (4) System	25 Mar 2021 16:09:46

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:20:24
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 16:09:46

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered		
'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered '25/Mar/2021 12:20'	(b) (4) System	25 Mar 2021 17:20:44

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:20:44

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered		
'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered '29/Mar/2021 13:08'	(b) (4) System	29 Mar 2021 17:08:24

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:44:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:35:56
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:08:24

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'USA-US106-2021-MRNA-1273-P301000011'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Yes (Y)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'No (N)'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Nadine'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Easton'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
Un-reviewed for Safety.	System	24 Mar 2021 17:12:19
DataPoint Un-verified.	System	24 Mar 2021 17:12:19
User entered 'Rouphael'	System	24 Mar 2021 17:12:19
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:10:04
User entered 'Beshears'	System	17 Feb 2021 15:03:05

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '500 Irvin Court'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'Decatur'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered 'GA'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:09:28
User entered '30030'	System	24 Mar 2021 17:12:19

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:34:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:05:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 16:46:42
User entered 'US'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	06 Apr 2021 19:22:37
User entered '9'	System	29 Mar 2021 17:08:24
User entered '8'	System	25 Mar 2021 17:20:44
User entered '7'	System	25 Mar 2021 16:09:46
User entered '6'	System	24 Mar 2021 17:12:19
User entered '5'	System	23 Mar 2021 13:36:43
User entered '4'	System	23 Mar 2021 12:17:51
User entered '3'	System	22 Mar 2021 13:32:09
User entered '2'	System	18 Feb 2021 16:47:14
User entered '1'	System	17 Feb 2021 15:10:13

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:44:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
User entered '06/Apr/2021 12:22'	(b) (4) System	06 Apr 2021 19:22:37

US3482302

Folder: SAE USA-US106-2021-MRNA-1273-P301000011

Form: Safety Report Form (10)

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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.	(b) (4), (b) (6)	21 Apr 2021 19:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:46
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37