

US3022167 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:46:53

All time stamps listed in this document are displayed in GMT

US3022167

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:02:32

Generated On: 09 Jun 2021 14:46:53

[Participant ID](#)

US3022167

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

US3022167

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3022167

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Date of Birth (MMM yyyy)	(b) (6) 1999
Age	21
Age Units	YEARS
Age (Derived)	21
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	HISPANIC
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 18:02:34

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Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 18:02:34

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 18:02:34

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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) 23 Feb 2021 18:02:34

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Condition	PRESENCE OF H. PYLORI INFECTION
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: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Condition	AMOXICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:02:34

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	17:28 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 17:28
Height (xxx.x)	156.7 cm
Weight (xxx.x)	51.9 kg
BMI (xxx.x)	21.13632 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:02:34

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 18:02:34

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Date of assessment (dd MMM yyyy) 17 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 18:02:34

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Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 17 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:02:34

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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) 23 Feb 2021 18:02:34

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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)	True
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)	False
Other	True
Specify	LIVES IN COMMUNITY ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:02:34

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

Visit date (dd MMM yyyy)	17 AUG 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) 23 Feb 2021 18:02:34

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What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 105284

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) 23 Feb 2021 18:02:34

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

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)	17 AUG 2020
Time of assessment (00:00-23:59)	17:28 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 17:28
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

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)	17 AUG 2020
Time of assessment (00:00-23:59)	19:33 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 19:33
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:02:34

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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: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 18:02:34

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Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

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) 17 AUG 2020

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

Treatment Date and Time (derived) 17 AUG 2020 18:59

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) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

18:17 (24 HR)

Collection date and time (derived)

17 AUG 2020 18:17

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:59	17 AUG 2020 17:59
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

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 14:46:53

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

99.0 °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

17 AUG 2020 19:34

PC Open Date & Time

17 AUG 2020 19:19

PC Close Date & Time

17 AUG 2020 21:49

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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	18 AUG 2020 09:05
PC Open Date & Time	17 AUG 2020 22:44
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

19 AUG 2020 07:20

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

97.7 °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

20 AUG 2020 07:36

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 11:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 12:14

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

98.7 °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

24 AUG 2020 11:05

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 19:23

PC Open Date & Time

17 AUG 2020 19:19

PC Close Date & Time

17 AUG 2020 21:49

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

18 AUG 2020 06:50

PC Open Date & Time

17 AUG 2020 22:44

PC Close Date & Time

18 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

19 AUG 2020 07:12

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

20 AUG 2020 07:36

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

21 AUG 2020 11:37

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 12:14

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

24 AUG 2020 11:05

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

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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 ☐

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 19:24
PC Open Date & Time	17 AUG 2020 19:19
PC Close Date & Time	17 AUG 2020 21:49

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 09:02
PC Open Date & Time	17 AUG 2020 22:44
PC Close Date & Time	18 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 07:13
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 07:37
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 11:37
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

Yes ☐

PC Time stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:15
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 11:06
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3022167

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:02:35

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:02:35

Generated On: 09 Jun 2021 14:46:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 15:19
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:02:35

Generated On: 09 Jun 2021 14:46:53

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	17:05 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 17:05
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3022167

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3022167

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 14 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 SEP 2020

What was the treatment time? (00:00-23:59) 16:35 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 16:35

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

US3022167

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

16:00 (24 HR)

Collection date and time (derived)

14 SEP 2020 16:00

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:49	14 SEP 2020 15:49
Nasopharyngeal Swab 2	No		

US3022167

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 16:55

PC Close Date & Time

14 SEP 2020 19:25

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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 100.7 °F

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

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

PC Time Stamp	15 SEP 2020 11:03
PC Open Date & Time	14 SEP 2020 20:20
PC Close Date & Time	15 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

98.6 °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

16 SEP 2020 11:18

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

18 SEP 2020 09:56

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

98.0 °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

19 SEP 2020 09:35

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

98.7 °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

20 SEP 2020 09:36

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

98.2 °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

21 SEP 2020 09:36

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 16:55

PC Close Date & Time

14 SEP 2020 19:25

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

15 SEP 2020 11:03

PC Open Date & Time

14 SEP 2020 20:20

PC Close Date & Time

15 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

16 SEP 2020 11:19

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

18 SEP 2020 09:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

19 SEP 2020 09:35

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

20 SEP 2020 09:36

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

21 SEP 2020 09:35

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 16:55

PC Close Date & Time

14 SEP 2020 19:25

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 11:04
PC Open Date & Time	14 SEP 2020 20:20
PC Close Date & Time	15 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 11:20
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

	Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 09:41
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 09:36
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 09:35
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 09:35
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3022167

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:02:35

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:02:35

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 09:30
Temperature (xxx.x)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022167

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:02:35

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

US3022167

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:02:35

Generated On: 09 Jun 2021 14:46:53

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

Collection date (dd MMM yyyy)	09 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	09:42 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	09 OCT 2020 09:42
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US3022167

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:35

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	True
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 OCT 2020 10:01:41
Patient Cloud Open Date & Time	17 OCT 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
117 of 2817	

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 17:59:24

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 17:44:13

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 92

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

No ☒

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 NOV 2020 09:08:56

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 07:20:57
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 12:08:37

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 07:51:45

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 11:16:05

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

16 DEC 2020 00:01:16

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

23 DEC 2020 08:55:22

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

30 DEC 2020 07:49:53

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 00:44:02

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 03:05:25

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 09:43:07

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

27 JAN 2021 04:59:30

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 08:01:51

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 00:41:35
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 FEB 2021 14:19:06
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 06:09:07

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 11:14:18

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 12:32:55

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 MAR 2021 06:19:19
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 MAR 2021 07:27:29
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	31 MAR 2021 02:08:11
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 APR 2021 06:27:54
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 01:21:57

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 09:49:19

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 10:24:16

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 264

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

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

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

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

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

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

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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13 JUN 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐ 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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐ 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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐
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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	19 SEP 2021 23:59
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US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	05 DEC 2021 23:59
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US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐
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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐
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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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°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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 544

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

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

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

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

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

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

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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°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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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°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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 726

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

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

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

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

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

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

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	24 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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="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"/>

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐
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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	16 OCT 2022 23:59
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US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 796

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3022167

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:46:53

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
Yes	No	03 MAR 2021 11:14:26

US3022167

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 22:59:26

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:17:45

Generated On: 09 Jun 2021 14:46:53

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) _____

US3022167

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 22:59:26

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 MAR 2021

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

US3022167

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 22:59:26

Generated On: 09 Jun 2021 14:46:53

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

Collection date (dd MMM yyyy)	01 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:45 (24 HR)
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Collection date and time (derived)	01 MAR 2021 10:45
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US3022167

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:59:26

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:17:45

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022167

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 22:17:45

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022167

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Date of Contact	19 OCT 2020
Time of Contact	12:00
Date and Time of Contact (derived)	19 OCT 2020 12:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input checked="" type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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"/>

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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"/>

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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 19 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Symptom Day

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

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

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Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	36.9 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Symptom Day

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

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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 OCT 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.1 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 19 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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 19 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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 OCT 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.3 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

	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 19 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

Date of Visit	21 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	21 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 11:16
Height (xxx.x)	156.7 cm
Weight (xxx.x)	49.7 kg
Temperature (xxx.x)	36.9 C
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3022167

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 OCT 2020

US3022167

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

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

Visit date (dd MMM yyyy)	04 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3022167

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Date of updated informed consent (dd MMM yyyy) 04 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 04 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 JAN 2021

Collection time (00:00-23:59)

10:04 (24 HR)

Collection date and time (derived)

04 JAN 2021 10:04

US3022167

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:02:34

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 JAN 2021
Collection time (00:00 - 23:59)	10:18
Collection Date and Time (derived)	04 JAN 2021 10:18

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:02:32

Generated On: 09 Jun 2021 14:46:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID

Adverse event DYSURIA

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) 18 AUG 2020

Start time (00:00-23:59) 08:00 (24 HR)

AE start date and time (derived) 18 AUG 2020 08:00

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 25 AUG 2020

End time (00:00-23:59) 08:00 (24 HR)

AE End Date and Time (derived) 25 AUG 2020 08:00

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 (1)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID	
Adverse event	DYSURIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID

Adverse event

YEAST INFECTION

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)

05 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID

Adverse event

ACUTE GASTRITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (8)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" 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 checked="" type="radio"/> Recovered/Resolved <input 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)	

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID	
Adverse event	COVID LIKE-ILLNESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 OCT 2020
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 (9)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID	
Adverse event	ANXIETY
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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 13 Apr 2021 22:17:36

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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 type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" 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 checked="" type="radio"/> Recovered/Resolved <input 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 (11)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID

Adverse event

DEHYDRATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 MAR 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 (11)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID

Adverse event

CHOLECYSTITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 MAR 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 (12)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
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"/>
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 (13)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID	USA-US051-2021-MRNA-1273-P30 1000007
Adverse event	DEHYDRATION
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)	19 MAR 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)	22 MAR 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 type="radio"/> Grade 4 <input checked="" 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)	19 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	22 MAR 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 (13)

Data signed: (b) (4) 13 Apr 2021 22:17:36

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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	
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: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

AEID	
Adverse event	ALLERGIC RHINITIS
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)	06 APR 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" 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 checked="" type="radio"/> Recovered/Resolved <input 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)	_____

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:02:33

Generated On: 09 Jun 2021 14:46:53

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

Yes ☒

No ☐

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

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication LEFT LEG SCIATIC NERVE PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (2)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication CLARITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication H-PYLORI

Dose per administration 125

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) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication ETONOGESTREL

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 68

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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	IMPLANT	
Start date (dd MMM yyyy)	24 APR 2019	
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) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication DYSURIA

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication DYSURIA

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 18 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION
SITE/HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)	14 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication DIFLUCAN

Prophylaxis Yes ☐
No ☒

Indication YEAST INFECTION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication PROMETHAZINE

Prophylaxis Yes ☐
No ☒

Indication VOMITING

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 (8)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication ACUTE GASTRITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication SUCRALFATE

Prophylaxis Yes ☐
No ☒

Indication ACUTE GASTRITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)	15 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
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) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 (11)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)	16 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTECTOMY

Dose per administration 5/325

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)	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)		
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 (13)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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 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)	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 (14)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACUTE GASTRITIS

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 (14)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)	15 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)	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) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication CLONAZEPAM

Prophylaxis Yes ☒
No ☐

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

AS DIRECTED

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

PRODUCTION RELEASE (v12.003

424 of 2817

EAB) (1725)

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Name of Medication CETIRIZINE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

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 ☐

PRODUCTION RELEASE (v12.003

426 of 2817

EAB) (1725)

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

	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)	06 APR 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"/>

US3022167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3022167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 MAR 2021	CHOLECYSTECTOMY	Adverse Event	

US3022167

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:46:53

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

US3022167

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US051-2020-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US051-2020-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/SEP/2020 10:24
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

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US051-2020-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/OCT/2020 13:43
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

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US051-2020-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/APR/2021 06:22
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

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US051-2020-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/APR/2021 07:04
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

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US051-2021-MRNA-1273-P301000007
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 22:17:36

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US051-2021-MRNA-1273-P301000007
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	09/APR/2021 07:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022167 (Prod: Meridian Clinical Research-Savannah)

US3022167

Form: Participant Creation

Generated On: 09 Jun 2021 14:46:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'US3022167'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	17 Aug 2020 21:49:17

US3022167

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:37:47
	(b) (4)	

US3022167

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 AUG 2020'	RWS_ENDPOINT	17 Aug 2020 21:49:18
	ENDPOINT (b) (4)	
	(b) (4)	

US3022167

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Clinic (Clinic)'	Chevon Roberts (b) (4)	17 Aug 2020 23:37:47
	(b) (4)	

US3022167

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'SCRN'	(b) (4), (b) (6) System	17 Aug 2020 23:37:47

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered (b) (6) 1999'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	17 Aug 2020 21:49:19

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '21'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'YEARS'	System	17 Aug 2020 23:38:04

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered '21'	(b) (4), (b) (6) System	17 Aug 2020 23:09:56

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Female (F)'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)' reason for change: Data Entry Error	Chevon Roberts (b) (4)	17 Aug 2020 23:41:59
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Chevon Roberts (b) (4)	17 Aug 2020 23:41:59
	(b) (4)	
User entered '1'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:38:04

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Chevon Roberts (b) (4)	17 Aug 2020 23:41:59
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'HISPANIC' reason for change: Data Entry Error	Chevon Roberts (b) (4)	17 Aug 2020 23:41:59
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:04
	(b) (4)	

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:09:56
	(b) (4)	

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'Aug 2020'	System	17 Aug 2020 23:09:56

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered '2020'	(b) (4), (b) (6) System	17 Aug 2020 23:09:56

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Amendment 2 (2)'	Chevon Roberts (b) (4)	17 Aug 2020 23:09:56
	(b) (4)	

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:09:56
	(b) (4)	

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:09:56
	(b) (4)	

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:09:56
	(b) (4)	

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:09:56
	(b) (4)	

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	RWS_ENDPOINT	17 Aug 2020 21:49:18
	ENDPOINT (b) (4)	
	(b) (4)	

US3022167

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'I'	(b) (4), (b) (6) System	17 Aug 2020 23:09:59

US3022167

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:09:59
	(b) (4)	

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Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:46:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:38:42
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatic neuralgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 13:44:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 13:44:46
User closed query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral SCIATIC NERVE. Update Med History eCRF as appropriate.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 18:22:51
' (Site from DM).		
Data point term sent to Coder	System	02 Oct 2020 18:15:40
Query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral SCIATIC NERVE. Update Med History eCRF as appropriate.	Stella Yoon (b) (4) (b) (4)	02 Oct 2020 18:15:06
' answered with 'updated' (Site from DM).		
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	02 Oct 2020 18:15:03
User entered 'left leg SCIATIC NERVE PAIN' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	02 Oct 2020 18:15:03
User opened query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral SCIATIC NERVE. Update Med History eCRF as appropriate.	(b) (4), (b) (6)	28 Aug 2020 10:00:07
' (Site from DM).		
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:08:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:08:29
Data point term sent to Coder	System	17 Aug 2020 23:39:22
User entered 'SCIATIC NERVE PAIN'	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:39:00

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'UN UNK 2015'	Chevon Roberts (b) (4)	17 Aug 2020 23:39:00
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:39:00

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:39:00
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:39:00
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:39:00
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'Jan 2015'	(b) (4), (b) (6) System	17 Aug 2020 23:39:00

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered '2015'	(b) (4), (b) (6) System	17 Aug 2020 23:39:00

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered empty.	(b) (4), (b) (6) System	17 Aug 2020 23:39:00

US3022167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered empty.	(b) (4), (b) (6) System	17 Aug 2020 23:39:00

US3022167

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Helicobacter infections, PT: Helicobacter infection, LLT: Helicobacter pylori infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:25:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:25:19
User closed query 'Per DM CLR: Please review and clarify this medical condition. Is this a positive H. Pylori serum test? Presence of H. Pylori infection? Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 18:23:05
Data point term sent to Coder	System	02 Oct 2020 12:59:22
Query 'Per DM CLR: Please review and clarify this medical condition. Is this a positive H. Pylori serum test? Presence of H. Pylori infection? Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	02 Oct 2020 12:59:06
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	02 Oct 2020 12:59:03
User entered 'Presence of H. Pylori infection' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	02 Oct 2020 12:59:03
User opened query 'Per DM CLR: Please review and clarify this medical condition. Is this a positive H. Pylori serum test? Presence of H. Pylori infection? Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 09:59:57
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Helicobacter infections, PT: Helicobacter infection, LLT: Helicobacter pylori infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:44:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:44:31
Data point term sent to Coder	System	17 Aug 2020 23:39:23
User entered 'H-PYLORIC'	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:39:17

US3022167

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'UN UNK 2017'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:39:17

US3022167

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:39:17
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:39:17

US3022167

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:39:17
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:39:17
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'Jan 2017'	System	17 Aug 2020 23:39:17

US3022167

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered '2017'	(b) (4), (b) (6) System	17 Aug 2020 23:39:17

US3022167

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered empty.	(b) (4), (b) (6) System	17 Aug 2020 23:39:17

US3022167

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered empty.	(b) (4), (b) (6) System	17 Aug 2020 23:39:17

US3022167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:41:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:41:15
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 23:40:23
User entered 'AMOXICILLIN ALLERGY'	Chevon Roberts (b) (4)	17 Aug 2020 23:39:36
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'UN UNK 2003'	Chevon Roberts (b) (4)	17 Aug 2020 23:39:36
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:39:36
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:39:36

US3022167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:39:36
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:39:36
	(b) (4)	

US3022167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'Jan 2003'	(b) (4), (b) (6) System	17 Aug 2020 23:39:36

US3022167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered '2003'	(b) (4), (b) (6) System	17 Aug 2020 23:39:36

US3022167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered empty.	(b) (4), (b) (6) System	17 Aug 2020 23:39:36

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered empty.	(b) (4), (b) (6) System	17 Aug 2020 23:39:36

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '17 Aug 2020'	(b) (4) Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:40:29

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17:28'	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered '17 Aug 2020 17:28'	(b) (4), (b) (6) System	17 Aug 2020 23:40:29

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '156.7' cm	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	
DataPoint set to visible.	System	17 Aug 2020 23:09:59

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '51.9' kg	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	
DataPoint set to visible.	System	17 Aug 2020 23:09:59

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
Amendment Manager: User entered '21.13632'	System	17 Sep 2020 00:01:13
User entered '21.1'	System	17 Aug 2020 23:40:29
DataPoint set to visible.	System	17 Aug 2020 23:09:59

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	17 Aug 2020 23:40:29
DataPoint set to visible.	System	17 Aug 2020 23:09:59

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:14:04
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 19:55:02
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 19:54:55
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:09:18
User entered '37.0' C	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:54:55
User entered 'Oral (Oral)'	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:54:55
User entered '70'	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'bpm'	(b) (4), (b) (6) System	17 Aug 2020 23:40:29

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:54:55
User entered '16'	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Aug 2020 23:40:29

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:54:55
User entered '113'	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 23:40:29

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:54:55
User entered '70'	Chevon Roberts (b) (4)	17 Aug 2020 23:40:29
	(b) (4)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 23:40:29

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	

US3022167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	

US3022167

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per CDM: Please note that Was the physical examination performed? is recorded as "Yes" at Visit 1 Day 1. Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be completed at Screening and recorded as "No" at Visit 1 Day 1. Please review and update accordingly, else clarify. ' (Site from DM). Query 'Per CDM: Please note that Was the physical examination performed? is recorded as "Yes" at Visit 1 Day 1. Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be completed at Screening and recorded as "No" at Visit 1 Day 1. Please review and update accordingly, else clarify. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 12:28:52
User entered 'Yes (Y)' reason for change: Per Query Resolution	Morgan Deal (b) (4)	13 Nov 2020 13:46:21
User opened query 'Per CDM: Please note that Was the physical examination performed? is recorded as "Yes" at Visit 1 Day 1. Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be completed at Screening and recorded as "No" at Visit 1 Day 1. Please review and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Deal (b) (4)	13 Nov 2020 13:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 16:53:14
	Shanice Bennett (b) (4)	24 Sep 2020 02:18:03
	(b) (4)	
	Chevon Roberts (b) (4)	17 Aug 2020 23:40:36
	(b) (4)	

US3022167

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 Aug 2020' reason for change: Per Query Resolution	Morgan Deal (b) (4)	13 Nov 2020 13:46:13
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	24 Sep 2020 02:18:03
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	24 Sep 2020 02:18:03
	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 21:49:10
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:40:36
	(b) (4)	

US3022167

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '17 Aug 2020'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:40:49

US3022167

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:40:49

US3022167

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:40:49
	(b) (4)	

US3022167

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:40:49
	(b) (4)	

US3022167

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:40:49

US3022167

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:40:49
	(b) (4)	

US3022167

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:40:49
	(b) (4)	

US3022167

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:40:49

US3022167

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:41:10

US3022167

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '17 Aug 2020'	(b) (4) Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:41:10

US3022167

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Urine (URINE)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:41:10

US3022167

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Negative (NEGATIVE)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:41:10

US3022167

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per CDM listing review: Was FSH sample collected? Is recorded as "NO", however collection date and collection time is present. Please review and update ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:56:39
Query 'Per CDM listing review: Was FSH sample collected? Is recorded as "NO", however collection date and collection time is present. Please review and update ' answered with 'done' (Site from DM).	Stella Yoon (b) (4)	31 Aug 2020 17:51:05
	(b) (4)	
User opened query 'Per CDM listing review: Was FSH sample collected? Is recorded as "NO", however collection date and collection time is present. Please review and update ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 13:42:14
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:41:10
	(b) (4)	

US3022167

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 17:51:02
	(b) (4)	
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:41:10
	(b) (4)	

US3022167

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 17:51:02
	(b) (4)	
User entered '17:44'	Chevon Roberts (b) (4)	17 Aug 2020 23:41:10
	(b) (4)	

US3022167

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User entered empty.	System	31 Aug 2020 17:51:02
User entered '17 Aug 2020 17:44'	System	17 Aug 2020 23:41:10

US3022167

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

US3022167

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

US3022167

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

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)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

US3022167

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

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)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

US3022167

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

US3022167

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[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)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:42:50

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:42:50

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:42:50

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

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)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[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)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'I'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:42:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'I'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:30:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'LIVES IN COMMUNITY ONGOING PERSON TO PERSON TRANSMISSION'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Clinic (Clinic)'	Chevon Roberts (b) (4)	17 Aug 2020 23:42:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'VISIT1'	(b) (4), (b) (6) System	17 Aug 2020 23:42:59

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 AUG 2020'	RWS_ENDPOINT	17 Aug 2020 22:29:17
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:10:56
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:10:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 22:29:17
User entered '105284' (non-conformant).	RWS_ENDPOINT (b) (4)	17 Aug 2020 22:29:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 22:29:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

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)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM: Please complete this section of the form, otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 09:07:13
Query 'Per CDM: Please complete this section of the form, otherwise explain.' answered with 'done' (Site from DM).	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 17:52:07
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 17:52:04
User opened query 'Per CDM: Please complete this section of the form, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 10:04:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

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)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4)	31 Aug 2020 17:52:04

US3022167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	31 Aug 2020 17:52:04
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	31 Aug 2020 17:52:04
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	31 Aug 2020 17:52:04
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:20:53
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 19:07:49
User entered 'No (N)'	Morgan Deal (b) (4)	12 Nov 2020 19:07:44
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:42:08
	(b) (4), (b) (6)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:24
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:45:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 05:20:04
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 19:53:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:53:45
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:57:58
User entered '156.7' cm	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:44:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:53:45
User entered '51.9' kg	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:20:04
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 19:53:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:53:45
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:57:58
User entered '156.7' cm	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:53:45
User entered '51.9' kg	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17:28'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '17 Aug 2020 17:28'	(b) (4), (b) (6)	
	System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '37.0' C	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (Oral)'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '70'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'bpm'	(b) (4), (b) (6) System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '16'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '113'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '70'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 05:20:04
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 19:53:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:53:45
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:57:58
User entered '156.7' cm	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 19:53:45
User entered '51.9' kg	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 14:32:27
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'SUBJECT WAITS 30 MINUTES' (Site from System).	Chevon Roberts (b) (4)	17 Aug 2020 23:44:31
	(b) (4)	
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 23:44:16
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 23:44:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 23:44:16
User entered '19:33' reason for change: Data Entry Error	Chevon Roberts (b) (4)	17 Aug 2020 23:44:16
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 23:44:09
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User entered '17 Aug 2020 19:33'	System	17 Aug 2020 23:44:16
User entered empty.	System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '37.2' C	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (Oral)'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '86'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User entered 'bpm'	System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '120'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '77'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 23:44:09

US3022167

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 12:28:47
Query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	13 Nov 2020 13:45:18
User entered 'No (N)' reason for change: Per Query Resolution	Morgan Deal (b) (4)	13 Nov 2020 13:45:13
User opened query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:21:06
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:42
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	13 Nov 2020 13:45:13
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:44:42
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and Was FSH sample collected? should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 06:26:46
Query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and Was FSH sample collected? should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 19:57:43
User entered 'No (N)' reason for change: Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 19:57:38
User opened query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and Was FSH sample collected? should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:21:24
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 19:57:38
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 19:57:38
User entered 'Urine (URINE)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 19:57:38
User entered 'Negative (NEGATIVE)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 19:57:38
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 19:57:38
User entered '17:44'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User entered empty.	System	12 Nov 2020 19:57:38
User entered '17 Aug 2020 17:44'	System	17 Aug 2020 23:45:13

US3022167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:10:22
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:10:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:10:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:10:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '18:59'	Chevon Roberts (b) (4)	17 Aug 2020 23:10:22
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '17 Aug 2020 18:59'	(b) (4), (b) (6)	
	System	17 Aug 2020 23:10:22

US3022167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Chevon Roberts (b) (4)	17 Aug 2020 23:10:22
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'ONCE'	System	17 Aug 2020 23:10:22

US3022167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:29
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:29
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '18:17'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:29
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User entered '17 Aug 2020 18:17'	System	17 Aug 2020 23:45:29

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 Aug 2020'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:43
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:43
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:43
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17:59'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:43
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '17 Aug 2020 17:59'	(b) (4), (b) (6)	
	System	17 Aug 2020 23:45:43

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:43
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:43
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	17 Aug 2020 23:45:43
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered empty.	(b) (4), (b) (6)	
	System	17 Aug 2020 23:45:43

US3022167

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	17 Aug 2020 23:45:47
	(b) (4)	

US3022167

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6) System	17 Aug 2020 23:45:47

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	17 Aug 2020 23:10:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:34:30', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a133e29b-96c1-45f3-aea4-db45690b9f38' User entered 'Yes (Y)'	(b) (4), (b) (6) System	17 Aug 2020 23:34:48
	System	17 Aug 2020 23:34:48

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:34:36', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a133e29b-96c1-45f3-aea4-db45690b9f38' User entered '99.0'	System	17 Aug 2020 23:34:48
	System	17 Aug 2020 23:34:48

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:34:42', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a133e29b-96c1-45f3-aea4-db45690b9f38' User entered 'No (N)'	System	17 Aug 2020 23:34:48
	System	17 Aug 2020 23:34:48

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:34:44', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a133e29b-96c1-45f3-aea4-db45690b9f38' User entered '17 Aug 2020 19:34'	(b) (4), (b) (6) System	17 Aug 2020 23:34:48
	System	17 Aug 2020 23:34:48

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Aug 2020 19:19'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Aug 2020 21:49'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:05:39', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a8d24096-c774-4841-9ff7-138bfb5265d2' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Aug 2020 13:05:52
	System	18 Aug 2020 13:05:52

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:05:43', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a8d24096-c774-4841-9ff7-138bfb5265d2' User entered '98.6'	(b) (4), (b) (6) System	18 Aug 2020 13:05:52
	System	18 Aug 2020 13:05:52

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:05:47', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a8d24096-c774-4841-9ff7-138bfb5265d2'	(b) (4), (b) (6)	
System		18 Aug 2020 13:05:52
User entered 'No (N)'	System	18 Aug 2020 13:05:52

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:05:50', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a8d24096-c774-4841-9ff7-138bfb5265d2'	(b) (4), (b) (6)	
	System	18 Aug 2020 13:05:52
User entered '18 Aug 2020 09:05'	System	18 Aug 2020 13:05:52

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Aug 2020 22:44'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	17 Aug 2020 23:10:22
	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:20:24', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a03999b4-f7bf-404e-8213-00f381fa970e' User entered 'Yes (Y)'	System	19 Aug 2020 11:20:37
	System	19 Aug 2020 11:20:37

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:20:28', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a03999b4-f7bf-404e-8213-00f381fa970e' User entered '97.8'	(b) (4), (b) (6) System	19 Aug 2020 11:20:37
	System	19 Aug 2020 11:20:37

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:20:31', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a03999b4-f7bf-404e-8213-00f381fa970e' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 11:20:37
	System	19 Aug 2020 11:20:37

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:20:34', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a03999b4-f7bf-404e-8213-00f381fa970e' User entered '19 Aug 2020 07:20'	(b) (4), (b) (6) System	19 Aug 2020 11:20:37
	System	19 Aug 2020 11:20:37

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 3'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:06', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '45bdfb98-c8c0-4aa5-9d9f-7acaa88d1e7c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Aug 2020 11:36:16
	System	20 Aug 2020 11:36:16

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:09', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '45bdfb98-c8c0-4aa5-9d9f-7acaa88d1e7c' User entered '97.7'	(b) (4), (b) (6) System	20 Aug 2020 11:36:16
	System	20 Aug 2020 11:36:16

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:11', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '45bdfb98-c8c0-4aa5-9d9f-7acaa88d1e7c' User entered 'No (N)'	System	20 Aug 2020 11:36:16
	System	20 Aug 2020 11:36:16

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:13', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '45bdfb98-c8c0-4aa5-9d9f-7acaa88d1e7c' User entered '20 Aug 2020 07:36'	(b) (4), (b) (6) System	20 Aug 2020 11:36:16
	System	20 Aug 2020 11:36:16

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 4'	System	17 Aug 2020 23:10:22
	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:36:15', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3f8d7c9a-bc41-4aee-a5da-66a96bc6588f' User entered 'Yes (Y)'	System	21 Aug 2020 15:36:28
	System	21 Aug 2020 15:36:28

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:36:20', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3f8d7c9a-bc41-4aee-a5da-66a96bc6588f' User entered '98.0'	System	21 Aug 2020 15:36:28
	System	21 Aug 2020 15:36:28

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:36:22', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3f8d7c9a-bc41-4aee-a5da-66a96bc6588f' User entered 'No (N)'	System	21 Aug 2020 15:36:28
	System	21 Aug 2020 15:36:28

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:36:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3f8d7c9a-bc41-4aee-a5da-66a96bc6588f' User entered '21 Aug 2020 11:36'	(b) (4), (b) (6) System	21 Aug 2020 15:36:28
	System	21 Aug 2020 15:36:28

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 5'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 6'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:41', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'cde721c0-4555-436e-937b-1512cd5476d8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 16:14:48
	System	22 Aug 2020 16:14:48

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:43', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'cde721c0-4555-436e-937b-1512cd5476d8' User entered '98.0'	(b) (4), (b) (6) System	22 Aug 2020 16:14:48
	System	22 Aug 2020 16:14:48

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:45', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'cde721c0-4555-436e-937b-1512cd5476d8'	(b) (4), (b) (6)	
System		22 Aug 2020 16:14:48
User entered 'No (N)'	System	22 Aug 2020 16:14:48

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:47', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'cde721c0-4555-436e-937b-1512cd5476d8' User entered '22 Aug 2020 12:14'	(b) (4), (b) (6) System	22 Aug 2020 16:14:48
	System	22 Aug 2020 16:14:48

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	17 Aug 2020 23:10:22
User entered 'Day 7'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:09', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '04accd79-995f-47bc-858a-ff168da2cf7c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Aug 2020 15:05:24
	System	24 Aug 2020 15:05:24

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:16', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '04accd79-995f-47bc-858a-ff168da2cf7c' User entered '98.7'	(b) (4), (b) (6) System	24 Aug 2020 15:05:24
	System	24 Aug 2020 15:05:24

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:20', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '04accd79-995f-47bc-858a-ff168da2cf7c' User entered 'No (N)'	System	24 Aug 2020 15:05:24
	System	24 Aug 2020 15:05:24

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:22', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '04accd79-995f-47bc-858a-ff168da2cf7c' User entered '24 Aug 2020 11:05'	(b) (4), (b) (6) System	24 Aug 2020 15:05:24
	System	24 Aug 2020 15:05:24

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:23:03', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '7c41da24-a1da-4e04-a7a8-119f487fab8a' User entered 'Does not interfere with activity (2)'	(b) (4), (b) (6) System	17 Aug 2020 23:23:49
	System	17 Aug 2020 23:23:49

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:23:10', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '7c41da24-a1da-4e04-a7a8-119f487fab8a' User entered 'No (N)'	System	17 Aug 2020 23:23:49
	System	17 Aug 2020 23:23:49

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:23:26', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '7c41da24-a1da-4e04-a7a8-119f487fab8a' User entered 'No (N)'	System	17 Aug 2020 23:23:49
	System	17 Aug 2020 23:23:49

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:23:34', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '7c41da24-a1da-4e04-a7a8-119f487fab8a' User entered 'None (1)'	(b) (4), (b) (6) System	17 Aug 2020 23:23:49
	System	17 Aug 2020 23:23:49

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:23:46', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '7c41da24-a1da-4e04-a7a8-119f487fab8a' User entered '17 Aug 2020 19:23'	(b) (4), (b) (6) System	17 Aug 2020 23:23:49
	System	17 Aug 2020 23:23:49

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Aug 2020 19:19'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Aug 2020 21:49'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T06:49:18', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ccf8d9be-1f6e-4be6-a7ad-61c234a5e62e' User entered 'Does not interfere with activity (2)'	(b) (4), (b) (6) System	18 Aug 2020 10:50:18
	System	18 Aug 2020 10:50:18

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T06:49:45', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ccf8d9be-1f6e-4be6-a7ad-61c234a5e62e' User entered 'No (N)'	System	18 Aug 2020 10:50:18
	System	18 Aug 2020 10:50:18

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T06:49:52', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ccf8d9be-1f6e-4be6-a7ad-61c234a5e62e' User entered 'No (N)'	System	18 Aug 2020 10:50:18
	System	18 Aug 2020 10:50:18

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T06:49:59', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ccf8d9be-1f6e-4be6-a7ad-61c234a5e62e' User entered 'None (1)'	(b) (4), (b) (6) System	18 Aug 2020 10:50:18
	System	18 Aug 2020 10:50:18

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T06:50:16', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ccf8d9be-1f6e-4be6-a7ad-61c234a5e62e' User entered '18 Aug 2020 06:50'	(b) (4), (b) (6) System	18 Aug 2020 10:50:18
	System	18 Aug 2020 10:50:18

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Aug 2020 22:44'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 2'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:07', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '930469be-678f-402a-848c-5c220c5bb6ea' User entered 'Does not interfere with activity (2)'	(b) (4), (b) (6) System	19 Aug 2020 11:12:36
	System	19 Aug 2020 11:12:36

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:11', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '930469be-678f-402a-848c-5c220c5bb6ea' User entered 'No (N)'	System	19 Aug 2020 11:12:36
	System	19 Aug 2020 11:12:36

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:14', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '930469be-678f-402a-848c-5c220c5bb6ea' User entered 'No (N)'	System	19 Aug 2020 11:12:36
	System	19 Aug 2020 11:12:36

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:19', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '930469be-678f-402a-848c-5c220c5bb6ea' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 11:12:36
	System	19 Aug 2020 11:12:36

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:32', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '930469be-678f-402a-848c-5c220c5bb6ea' User entered '19 Aug 2020 07:12'	(b) (4), (b) (6) System	19 Aug 2020 11:12:36
	System	19 Aug 2020 11:12:36

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	17 Aug 2020 23:10:22
User entered 'Day 3'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:23', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0650dfdc-b795-4635-aef6-491cc0e5ae9c' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 11:36:43
	System	20 Aug 2020 11:36:43

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0650dfdc-b795-4635-aef6-491cc0e5ae9c' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 11:36:43
	System	20 Aug 2020 11:36:43

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:27', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0650dfdc-b795-4635-aef6-491cc0e5ae9c' User entered 'No (N)'	System	20 Aug 2020 11:36:43
	System	20 Aug 2020 11:36:43

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:37', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0650dfdc-b795-4635-aef6-491cc0e5ae9c'	(b) (4), (b) (6)	
	System	20 Aug 2020 11:36:43
User entered 'None (1)'	System	20 Aug 2020 11:36:43

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:39', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0650dfdc-b795-4635-aef6-491cc0e5ae9c' User entered '20 Aug 2020 07:36'	(b) (4), (b) (6) System	20 Aug 2020 11:36:43
	System	20 Aug 2020 11:36:43

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 4'	System	17 Aug 2020 23:10:22
	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:36:50', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bd916479-cf7e-42b6-ac32-b3d6f00fb2e3'	(b) (4), (b) (6) System	21 Aug 2020 15:37:31
User entered 'None (1)'	System	21 Aug 2020 15:37:31

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:36:52', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bd916479-cf7e-42b6-ac32-b3d6f00fb2e3' User entered 'No (N)'	System	21 Aug 2020 15:37:31
	System	21 Aug 2020 15:37:31

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:16', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bd916479-cf7e-42b6-ac32-b3d6f00fb2e3'	(b) (4), (b) (6) System	21 Aug 2020 15:37:31
User entered 'No (N)'	System	21 Aug 2020 15:37:31

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:22', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bd916479-cf7e-42b6-ac32-b3d6f00fb2e3'	(b) (4), (b) (6) System	21 Aug 2020 15:37:31
User entered 'None (1)'	System	21 Aug 2020 15:37:31

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bd916479-cf7e-42b6-ac32-b3d6f00fb2e3'	(b) (4), (b) (6)	
	System	21 Aug 2020 15:37:31
User entered '21 Aug 2020 11:37'	System	21 Aug 2020 15:37:31

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 5'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 6'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:50', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1f0d5074-0635-4946-9508-12229566435c' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 16:14:59
	System	22 Aug 2020 16:14:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:52', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1f0d5074-0635-4946-9508-12229566435c'	(b) (4), (b) (6)	
	System	22 Aug 2020 16:14:59
User entered 'No (N)'	System	22 Aug 2020 16:14:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1f0d5074-0635-4946-9508-12229566435c'	(b) (4), (b) (6)	
User entered 'No (N)'	System	22 Aug 2020 16:14:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:55', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1f0d5074-0635-4946-9508-12229566435c' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 16:14:59
	System	22 Aug 2020 16:14:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:57', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1f0d5074-0635-4946-9508-12229566435c' User entered '22 Aug 2020 12:14'	(b) (4), (b) (6) System	22 Aug 2020 16:14:59
	System	22 Aug 2020 16:14:59

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 7'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '25e35617-ec06-49c8-ac18-38342b74574b' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 15:05:50
	System	24 Aug 2020 15:05:50

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:29', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '25e35617-ec06-49c8-ac18-38342b74574b' User entered 'No (N)'	System	24 Aug 2020 15:05:50
	System	24 Aug 2020 15:05:50

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:33', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '25e35617-ec06-49c8-ac18-38342b74574b' User entered 'No (N)'	System	24 Aug 2020 15:05:50
	System	24 Aug 2020 15:05:50

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:34', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '25e35617-ec06-49c8-ac18-38342b74574b' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 15:05:50
	System	24 Aug 2020 15:05:50

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:48', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '25e35617-ec06-49c8-ac18-38342b74574b' User entered '24 Aug 2020 11:05'	(b) (4), (b) (6) System	24 Aug 2020 15:05:50
	System	24 Aug 2020 15:05:50

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:23:52', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3d26735a-b4fe-41bd-9d86-f041dc63eb91' User entered 'None (0)'	System	17 Aug 2020 23:24:32
	System	17 Aug 2020 23:24:32

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:24:00', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3d26735a-b4fe-41bd-9d86-f041dc63eb91' User entered 'No interference with activity (1)'	System	17 Aug 2020 23:24:32
	System	17 Aug 2020 23:24:32

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:24:04', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3d26735a-b4fe-41bd-9d86-f041dc63eb91' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 23:24:32
	System	17 Aug 2020 23:24:32

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:24:06', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3d26735a-b4fe-41bd-9d86-f041dc63eb91' User entered 'None (0)'	System	17 Aug 2020 23:24:32
	System	17 Aug 2020 23:24:32

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:24:12', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3d26735a-b4fe-41bd-9d86-f041dc63eb91' User entered 'None (0)'	System	17 Aug 2020 23:24:32
	System	17 Aug 2020 23:24:32

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:24:15', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3d26735a-b4fe-41bd-9d86-f041dc63eb91'	(b) (4), (b) (6)	
	System	17 Aug 2020 23:24:32
User entered 'No interference with activity (1)'	System	17 Aug 2020 23:24:32

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:24:23', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3d26735a-b4fe-41bd-9d86-f041dc63eb91' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 23:24:32
	System	17 Aug 2020 23:24:32

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-17T19:24:30', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3d26735a-b4fe-41bd-9d86-f041dc63eb91' User entered '17 Aug 2020 19:24'	(b) (4), (b) (6) System	17 Aug 2020 23:24:32
	System	17 Aug 2020 23:24:32

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Aug 2020 19:19'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Aug 2020 21:49'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T07:00:24', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0ffcce28-c63a-4401-a924-bb0dc4ccbe1e' User entered 'None (0)'	System	18 Aug 2020 13:02:54
	System	18 Aug 2020 13:02:54

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T07:00:32', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0ffcce28-c63a-4401-a924-bb0dc4ccbe1e' User entered 'No interference with activity (1)'	System	18 Aug 2020 13:02:54
	System	18 Aug 2020 13:02:54

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:02:12', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0ffcce28-c63a-4401-a924-bb0dc4ccbe1e' User entered 'None (0)'	System	18 Aug 2020 13:02:54
	System	18 Aug 2020 13:02:54

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:02:16', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0ffcce28-c63a-4401-a924-bb0dc4ccbe1e' User entered 'None (0)'	System	18 Aug 2020 13:02:54
	System	18 Aug 2020 13:02:54

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:02:29', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0ffcce28-c63a-4401-a924-bb0dc4ccbe1e'	(b) (4), (b) (6)	
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	18 Aug 2020 13:02:54

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:02:33', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0ffcce28-c63a-4401-a924-bb0dc4ccbe1e'	(b) (4), (b) (6)	
	System	18 Aug 2020 13:02:54
User entered 'No interference with activity (1)'	System	18 Aug 2020 13:02:54

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:02:42', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0ffcce28-c63a-4401-a924-bb0dc4ccbe1e' User entered 'No (N)'	System	18 Aug 2020 13:02:54
	System	18 Aug 2020 13:02:54

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-18T09:02:53', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0ffcce28-c63a-4401-a924-bb0dc4ccbe1e' User entered '18 Aug 2020 09:02'	(b) (4), (b) (6) System	18 Aug 2020 13:02:54
	System	18 Aug 2020 13:02:54

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Aug 2020 22:44'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	17 Aug 2020 23:10:22
	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:38', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bceba03-69b0-441d-beab-13529a18d62a' User entered 'None (0)'	System	19 Aug 2020 11:13:13
	System	19 Aug 2020 11:13:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:41', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bceba03-69b0-441d-beab-13529a18d62a'	(b) (4), (b) (6)	
System		19 Aug 2020 11:13:13
User entered 'Some interference with activity (2)'	System	19 Aug 2020 11:13:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:45', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bceba03-69b0-441d-beab-13529a18d62a'	(b) (4), (b) (6)	
System		19 Aug 2020 11:13:13
User entered 'Some interference with activity (2)'	System	19 Aug 2020 11:13:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:52', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bceba03-69b0-441d-beab-13529a18d62a' User entered 'None (0)'	System	19 Aug 2020 11:13:13
	System	19 Aug 2020 11:13:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bceba03-69b0-441d-beab-13529a18d62a'	(b) (4), (b) (6)	
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Aug 2020 11:13:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:12:57', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bceba03-69b0-441d-beab-13529a18d62a'	(b) (4), (b) (6)	
	System	19 Aug 2020 11:13:13
User entered 'No interference with activity (1)'	System	19 Aug 2020 11:13:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:13:02', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bceba03-69b0-441d-beab-13529a18d62a' User entered 'No (N)'	System	19 Aug 2020 11:13:13
	System	19 Aug 2020 11:13:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-19T07:13:11', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'bceba03-69b0-441d-beab-13529a18d62a' User entered '19 Aug 2020 07:13'	(b) (4), (b) (6) System	19 Aug 2020 11:13:13
	System	19 Aug 2020 11:13:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 3'	System	17 Aug 2020 23:10:22
	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:43', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '600c611a-b729-4c19-8f52-356671e05280' User entered 'None (0)'	System	20 Aug 2020 11:37:13
	System	20 Aug 2020 11:37:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:46', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '600c611a-b729-4c19-8f52-356671e05280'	(b) (4), (b) (6)	
	System	20 Aug 2020 11:37:13
User entered 'No interference with activity (1)'	System	20 Aug 2020 11:37:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:49', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '600c611a-b729-4c19-8f52-356671e05280'	(b) (4), (b) (6)	
System		20 Aug 2020 11:37:13
User entered 'No interference with activity (1)'	System	20 Aug 2020 11:37:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:51', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '600c611a-b729-4c19-8f52-356671e05280' User entered 'None (0)'	System	20 Aug 2020 11:37:13
	System	20 Aug 2020 11:37:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:55', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '600c611a-b729-4c19-8f52-356671e05280'	(b) (4), (b) (6)	
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Aug 2020 11:37:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:36:59', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '600c611a-b729-4c19-8f52-356671e05280' User entered 'None (0)'	System	20 Aug 2020 11:37:13
	System	20 Aug 2020 11:37:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:37:02', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '600c611a-b729-4c19-8f52-356671e05280' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 11:37:13
	System	20 Aug 2020 11:37:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-20T07:37:09', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '600c611a-b729-4c19-8f52-356671e05280' User entered '20 Aug 2020 07:37'	(b) (4), (b) (6) System	20 Aug 2020 11:37:13
	System	20 Aug 2020 11:37:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 4'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:33', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0747b6a7-f936-42d3-9208-4409127fdd5c' User entered 'None (0)'	System	21 Aug 2020 15:37:57
	System	21 Aug 2020 15:37:57

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:39', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0747b6a7-f936-42d3-9208-4409127fdd5c' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 15:37:57
	System	21 Aug 2020 15:37:57

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:41', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0747b6a7-f936-42d3-9208-4409127fdd5c' User entered 'None (0)'	System	21 Aug 2020 15:37:57
	System	21 Aug 2020 15:37:57

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:43', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0747b6a7-f936-42d3-9208-4409127fdd5c' User entered 'None (0)'	System	21 Aug 2020 15:37:57
	System	21 Aug 2020 15:37:57

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:45', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0747b6a7-f936-42d3-9208-4409127fdd5c' User entered 'None (0)'	System	21 Aug 2020 15:37:57
	System	21 Aug 2020 15:37:57

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:46', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0747b6a7-f936-42d3-9208-4409127fdd5c' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 15:37:57
	System	21 Aug 2020 15:37:57

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:50', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0747b6a7-f936-42d3-9208-4409127fdd5c' User entered 'No (N)'	System	21 Aug 2020 15:37:57
	System	21 Aug 2020 15:37:57

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-21T11:37:55', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0747b6a7-f936-42d3-9208-4409127fdd5c' User entered '21 Aug 2020 11:37'	(b) (4), (b) (6) System	21 Aug 2020 15:37:57
	System	21 Aug 2020 15:37:57

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 5'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	17 Aug 2020 23:10:22
User entered 'Day 6'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:14:59', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '6cf656db-48e8-4b5e-840c-855ef7ee91f2' User entered 'None (0)'	System	22 Aug 2020 16:15:13
	System	22 Aug 2020 16:15:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:15:01', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '6cf656db-48e8-4b5e-840c-855ef7ee91f2' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 16:15:13
	System	22 Aug 2020 16:15:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:15:02', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '6cf656db-48e8-4b5e-840c-855ef7ee91f2' User entered 'None (0)'	System	22 Aug 2020 16:15:13
	System	22 Aug 2020 16:15:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:15:03', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '6cf656db-48e8-4b5e-840c-855ef7ee91f2' User entered 'None (0)'	System	22 Aug 2020 16:15:13
	System	22 Aug 2020 16:15:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:15:04', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '6cf656db-48e8-4b5e-840c-855ef7ee91f2' User entered 'None (0)'	System	22 Aug 2020 16:15:13
	System	22 Aug 2020 16:15:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:15:05', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '6cf656db-48e8-4b5e-840c-855ef7ee91f2' User entered 'None (0)'	System	22 Aug 2020 16:15:13
	System	22 Aug 2020 16:15:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:15:07', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '6cf656db-48e8-4b5e-840c-855ef7ee91f2' User entered 'No (N)'	System	22 Aug 2020 16:15:13
	System	22 Aug 2020 16:15:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-22T12:15:10', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '6cf656db-48e8-4b5e-840c-855ef7ee91f2' User entered '22 Aug 2020 12:15'	(b) (4), (b) (6) System	22 Aug 2020 16:15:13
	System	22 Aug 2020 16:15:13

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	17 Aug 2020 23:10:22
User entered 'Day 7'	System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:51', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '94a1af40-8d3f-4f60-957f-f2f79dc866f6' User entered 'None (0)'	System	24 Aug 2020 15:06:41
	System	24 Aug 2020 15:06:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:05:53', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '94a1af40-8d3f-4f60-957f-f2f79dc866f6' User entered 'None (0)'	System	24 Aug 2020 15:06:41
	System	24 Aug 2020 15:06:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:06:08', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '94a1af40-8d3f-4f60-957f-f2f79dc866f6' User entered 'None (0)'	System	24 Aug 2020 15:06:41
	System	24 Aug 2020 15:06:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:06:21', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '94a1af40-8d3f-4f60-957f-f2f79dc866f6' User entered 'None (0)'	System	24 Aug 2020 15:06:41
	System	24 Aug 2020 15:06:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:06:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '94a1af40-8d3f-4f60-957f-f2f79dc866f6' User entered 'None (0)'	System	24 Aug 2020 15:06:41
	System	24 Aug 2020 15:06:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:06:27', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '94a1af40-8d3f-4f60-957f-f2f79dc866f6' User entered 'None (0)'	System	24 Aug 2020 15:06:41
	System	24 Aug 2020 15:06:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:06:30', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '94a1af40-8d3f-4f60-957f-f2f79dc866f6' User entered 'No (N)'	System	24 Aug 2020 15:06:41
	System	24 Aug 2020 15:06:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-08-24T11:06:39', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '94a1af40-8d3f-4f60-957f-f2f79dc866f6' User entered '24 Aug 2020 11:06'	(b) (4), (b) (6) System	24 Aug 2020 15:06:41
	System	24 Aug 2020 15:06:41

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	25 Aug 2020 11:20:58
	(b) (4)	

US3022167

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '24 Aug 2020'	Shanice Bennett (b) (4)	25 Aug 2020 11:20:58
	(b) (4)	

US3022167

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4)	25 Aug 2020 11:20:58
	(b) (4)	

US3022167

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 11:20:58
	(b) (4)	

US3022167

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	25 Aug 2020 11:21:01
	(b) (4)	

US3022167

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6) System	25 Aug 2020 11:21:01

US3022167

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	14 Sep 2020 20:41:20
	(b) (4)	

US3022167

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '31 Aug 2020'	Chevon Roberts (b) (4)	14 Sep 2020 20:41:20
	(b) (4)	

US3022167

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chevon Roberts (b) (4)	14 Sep 2020 20:41:20
	(b) (4)	

US3022167

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	14 Sep 2020 20:41:20
	(b) (4)	

US3022167

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	14 Sep 2020 20:41:23
	(b) (4)	

US3022167

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6) System	14 Sep 2020 20:41:23

US3022167

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	14 Sep 2020 20:41:35
	(b) (4)	

US3022167

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 20:41:47
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	14 Sep 2020 20:41:47
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	14 Sep 2020 20:41:47
User entered '08 Sep 2020' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	14 Sep 2020 20:41:47
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	14 Sep 2020 20:41:35
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 20:41:35
User entered '28 Sep 2020'	Chevon Roberts (b) (4) (b) (4)	14 Sep 2020 20:41:35

US3022167

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chevon Roberts (b) (4)	14 Sep 2020 20:41:35
	(b) (4)	

US3022167

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	14 Sep 2020 20:41:35
	(b) (4)	

US3022167

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	14 Sep 2020 20:41:53
	(b) (4)	

US3022167

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 20:41:53
	System	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Sep 2020 21:49:10
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14 Sep 2020'	Shanice Bennett (b) (4)	16 Sep 2020 21:49:10
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4)	16 Sep 2020 21:49:10
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'VISIT2'	(b) (4), (b) (6) System	16 Sep 2020 21:49:10

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14 Sep 2020'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '15:19'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '14 Sep 2020 15:19'	(b) (4), (b) (6)	
	System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '36.7' C	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '72'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'bpm'	(b) (4), (b) (6) System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '108'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '81'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14 Sep 2020'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17:05'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '14 Sep 2020 17:05'	(b) (4), (b) (6)	
	System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '37.3' C	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '68'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'bpm'	(b) (4), (b) (6) System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '108'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '76'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:05
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 21:58:05

US3022167

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Sep 2020 21:56:42
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14 Sep 2020'	Shanice Bennett (b) (4)	16 Sep 2020 21:56:42
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Sep 2020 21:49:44
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14 Sep 2020'	Shanice Bennett (b) (4)	16 Sep 2020 21:49:44
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Urine (URINE)'	Shanice Bennett (b) (4)	16 Sep 2020 21:49:44
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Shanice Bennett (b) (4)	16 Sep 2020 21:49:44
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". If "Yes", provide the collection date and time. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:34:48
Query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". If "Yes", provide the collection date and time. Please update as appropriate. ' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 14:48:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 14:48:49
User opened query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". If "Yes", provide the collection date and time. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:20:06
User entered empty.	Shanice Bennett (b) (4)	16 Sep 2020 21:49:44

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	16 Sep 2020 21:49:44
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	16 Sep 2020 21:49:44
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 21:49:44
	System	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	14 Sep 2020 20:42:19
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	14 Sep 2020 20:42:19
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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)	27 Mar 2021 16:32:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	14 Sep 2020 20:42:19

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14 Sep 2020'	Chevon Roberts (b) (4)	14 Sep 2020 20:42:19
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '16:35'	Chevon Roberts (b) (4)	14 Sep 2020 20:42:19
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '14 Sep 2020 16:35'	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Chevon Roberts (b) (4)	14 Sep 2020 20:42:19
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'ONCE'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Sep 2020 21:50:11
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:13:44
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'AN UNSCHEUDLE KIT WAS USED FOR THIS VISIT' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 14:49:48
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:28:56
User entered '14 Sep 2020'	Shanice Bennett (b) (4)	16 Sep 2020 21:50:11
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '16:00'	Shanice Bennett (b) (4)	16 Sep 2020 21:50:11
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '14 Sep 2020 16:00'	(b) (4), (b) (6)	
	System	16 Sep 2020 21:50:11

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per GCL Lab Rec: it appears GCL has this as an Unscheduled Visit with date of 14SEP2020. Please confirm this date is for Day 29 or clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:13:13
Query 'Per GCL Lab Rec: it appears GCL has this as an Unscheduled Visit with date of 14SEP2020. Please confirm this date is for Day 29 or clarify.'	Shanice Bennett (b) (4)	13 Nov 2020 14:50:35
answered with 'HAS AN UNSCHEUDLE KIT WAS USED FOR VISIT 2' (Site from DM).	(b) (4)	
User opened query 'Per GCL Lab Rec: it appears GCL has this as an Unscheduled Visit with date of 14SEP2020. Please confirm this date is for Day 29 or clarify.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 17:52:49
User entered '14 Sep 2020'	Shanice Bennett (b) (4)	16 Sep 2020 21:56:28
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shanice Bennett (b) (4)	16 Sep 2020 21:56:28
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Sep 2020 21:56:28
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '15:49'	Shanice Bennett (b) (4)	16 Sep 2020 21:56:28
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '14 Sep 2020 15:49'	(b) (4), (b) (6)	
	System	16 Sep 2020 21:56:28

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shanice Bennett (b) (4)	16 Sep 2020 21:56:28
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Sep 2020 21:56:28
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	16 Sep 2020 21:56:28
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered empty.	(b) (4), (b) (6)	
	System	16 Sep 2020 21:56:28

US3022167

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Sep 2020 21:56:33
	(b) (4)	

US3022167

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6)	16 Sep 2020 21:56:33
	System	

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '14 Sep 2020 16:55'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '14 Sep 2020 19:25'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:02:42', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '8c3efe84-7113-4da3-9e57-3c963f1b75b9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 15:03:09
	System	15 Sep 2020 15:03:09

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:02:49', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '8c3efe84-7113-4da3-9e57-3c963f1b75b9' User entered '100.7'	System	15 Sep 2020 15:03:09
	System	15 Sep 2020 15:03:09

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:03:01', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '8c3efe84-7113-4da3-9e57-3c963f1b75b9' User entered 'No (N)'	System	15 Sep 2020 15:03:09
	System	15 Sep 2020 15:03:09

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:03:03', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '8c3efe84-7113-4da3-9e57-3c963f1b75b9' User entered '15 Sep 2020 11:03'	(b) (4), (b) (6) System	15 Sep 2020 15:03:09
	System	15 Sep 2020 15:03:09

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '14 Sep 2020 20:20'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 2'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:17:07', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4416eaa1-1e50-41c1-a5c7-961ce698b8d3' User entered 'Yes (Y)'	System	16 Sep 2020 15:18:09
	System	16 Sep 2020 15:18:09

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:17:35', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4416eaa1-1e50-41c1-a5c7-961ce698b8d3' User entered '98.6'	System	16 Sep 2020 15:18:09
	System	16 Sep 2020 15:18:09

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:17:37', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4416eaa1-1e50-41c1-a5c7-961ce698b8d3'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Sep 2020 15:18:09

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:18:06', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4416eaa1-1e50-41c1-a5c7-961ce698b8d3' User entered '16 Sep 2020 11:18'	System	16 Sep 2020 15:18:09
	System	16 Sep 2020 15:18:09

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 3'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 4'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:44:47', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a7720466-cadb-4366-8ab8-6e680c5a4ac8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Sep 2020 13:57:02
	System	18 Sep 2020 13:57:02

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:56:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a7720466-cadb-4366-8ab8-6e680c5a4ac8' User entered '97.8'	System	18 Sep 2020 13:57:02
	System	18 Sep 2020 13:57:02

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:56:56', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a7720466-cadb-4366-8ab8-6e680c5a4ac8'	(b) (4), (b) (6)	
System		18 Sep 2020 13:57:02
User entered 'No (N)'	System	18 Sep 2020 13:57:02

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:56:57', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a7720466-cadb-4366-8ab8-6e680c5a4ac8' User entered '18 Sep 2020 09:56'	(b) (4), (b) (6) System	18 Sep 2020 13:57:02
	System	18 Sep 2020 13:57:02

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 5'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:35:26', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4b52b76a-8c6f-4303-9c34-8e566f86450c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Sep 2020 13:35:39
	System	19 Sep 2020 13:35:39

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:35:30', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4b52b76a-8c6f-4303-9c34-8e566f86450c' User entered '98.0'	System	19 Sep 2020 13:35:39
	System	19 Sep 2020 13:35:39

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:35:33', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4b52b76a-8c6f-4303-9c34-8e566f86450c' User entered 'No (N)'	System	19 Sep 2020 13:35:39
	System	19 Sep 2020 13:35:39

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:35:36', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4b52b76a-8c6f-4303-9c34-8e566f86450c' User entered '19 Sep 2020 09:35'	(b) (4), (b) (6) System	19 Sep 2020 13:35:39
	System	19 Sep 2020 13:35:39

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 6'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:36:17', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'c05aa0b6-8ec1-4fb3-9277-33a9ce20c461' User entered 'Yes (Y)'	System	20 Sep 2020 13:36:37
	System	20 Sep 2020 13:36:37

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:36:30', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'c05aa0b6-8ec1-4fb3-9277-33a9ce20c461' User entered '98.7'	(b) (4), (b) (6) System	20 Sep 2020 13:36:37
	System	20 Sep 2020 13:36:37

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:36:32', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'c05aa0b6-8ec1-4fb3-9277-33a9ce20c461' User entered 'No (N)'	System	20 Sep 2020 13:36:37
	System	20 Sep 2020 13:36:37

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:36:34', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'c05aa0b6-8ec1-4fb3-9277-33a9ce20c461' User entered '20 Sep 2020 09:36'	(b) (4), (b) (6) System	20 Sep 2020 13:36:37
	System	20 Sep 2020 13:36:37

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 7'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '686160f2-4e62-47f2-b530-5dae7c40ea4c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Sep 2020 13:36:45
	System	21 Sep 2020 13:36:45

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:36:35', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '686160f2-4e62-47f2-b530-5dae7c40ea4c' User entered '98.2'	System	21 Sep 2020 13:36:45
	System	21 Sep 2020 13:36:45

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:36:37', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '686160f2-4e62-47f2-b530-5dae7c40ea4c' User entered 'No (N)'	System	21 Sep 2020 13:36:45
	System	21 Sep 2020 13:36:45

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:36:43', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '686160f2-4e62-47f2-b530-5dae7c40ea4c' User entered '21 Sep 2020 09:36'	(b) (4), (b) (6) System	21 Sep 2020 13:36:45
	System	21 Sep 2020 13:36:45

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '14 Sep 2020 16:55'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '14 Sep 2020 19:25'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:03:22', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1c3c6709-6abd-4ffb-822c-1ed67f897f47'	(b) (4), (b) (6)	15 Sep 2020 15:03:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	15 Sep 2020 15:03:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:03:26', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1c3c6709-6abd-4ffb-822c-1ed67f897f47'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Sep 2020 15:03:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:03:35', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1c3c6709-6abd-4ffb-822c-1ed67f897f47' User entered 'No (N)'	System	15 Sep 2020 15:03:55
	System	15 Sep 2020 15:03:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:03:47', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1c3c6709-6abd-4ffb-822c-1ed67f897f47'	(b) (4), (b) (6) System	15 Sep 2020 15:03:55
User entered 'None (1)'	System	15 Sep 2020 15:03:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:03:49', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1c3c6709-6abd-4ffb-822c-1ed67f897f47' User entered '15 Sep 2020 11:03'	(b) (4), (b) (6) System	15 Sep 2020 15:03:55
	System	15 Sep 2020 15:03:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '14 Sep 2020 20:20'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 2'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:18:34', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f2420070-a9bf-4b02-a629-ea738943f96b'	(b) (4), (b) (6)	
	System	16 Sep 2020 15:19:44
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	16 Sep 2020 15:19:44

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:18:37', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f2420070-a9bf-4b02-a629-ea738943f96b' User entered 'No (N)'	System	16 Sep 2020 15:19:44
	System	16 Sep 2020 15:19:44

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:19:11', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f2420070-a9bf-4b02-a629-ea738943f96b' User entered 'No (N)'	System	16 Sep 2020 15:19:44
	System	16 Sep 2020 15:19:44

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:19:36', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f2420070-a9bf-4b02-a629-ea738943f96b'	(b) (4), (b) (6) System	16 Sep 2020 15:19:44
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 15:19:44

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:19:42', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f2420070-a9bf-4b02-a629-ea738943f96b' User entered '16 Sep 2020 11:19'	(b) (4), (b) (6) System	16 Sep 2020 15:19:44
	System	16 Sep 2020 15:19:44

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 3'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 4'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:44:29', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ddcba965-b177-4188-89d1-3f37e1fe1d48'	(b) (4), (b) (6)	
	System	18 Sep 2020 13:44:46
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	18 Sep 2020 13:44:46

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:44:31', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ddcba965-b177-4188-89d1-3f37e1fe1d48'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Sep 2020 13:44:46
	System	18 Sep 2020 13:44:46

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:44:34', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ddcba965-b177-4188-89d1-3f37e1fe1d48' User entered 'No (N)'	System	18 Sep 2020 13:44:46
	System	18 Sep 2020 13:44:46

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:44:40', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ddcba965-b177-4188-89d1-3f37e1fe1d48'	(b) (4), (b) (6) System	18 Sep 2020 13:44:46
User entered 'None (1)'	System	18 Sep 2020 13:44:46

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:44:41', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'ddcba965-b177-4188-89d1-3f37e1fe1d48' User entered '18 Sep 2020 09:44'	System	18 Sep 2020 13:44:46
	System	18 Sep 2020 13:44:46

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 5'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:35:45', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '34b140ca-785b-4cd7-b562-81be8847ca97'	(b) (4), (b) (6)	
	System	19 Sep 2020 13:35:55
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 13:35:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:35:47', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '34b140ca-785b-4cd7-b562-81be8847ca97' User entered 'No (N)'	System	19 Sep 2020 13:35:55
	System	19 Sep 2020 13:35:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:35:49', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '34b140ca-785b-4cd7-b562-81be8847ca97' User entered 'No (N)'	System	19 Sep 2020 13:35:55
	System	19 Sep 2020 13:35:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:35:51', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '34b140ca-785b-4cd7-b562-81be8847ca97'	(b) (4), (b) (6)	
User entered 'None (1)'	System	19 Sep 2020 13:35:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:35:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '34b140ca-785b-4cd7-b562-81be8847ca97' User entered '19 Sep 2020 09:35'	(b) (4), (b) (6) System	19 Sep 2020 13:35:55
	System	19 Sep 2020 13:35:55

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 6'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:51', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'e0039911-6613-46f2-a475-1e5831734061' User entered 'None (1)'	(b) (4), (b) (6) System	20 Sep 2020 13:36:14
	System	20 Sep 2020 13:36:14

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:56', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'e0039911-6613-46f2-a475-1e5831734061' User entered 'No (N)'	(b) (4), (b) (6) System	20 Sep 2020 13:36:14
	System	20 Sep 2020 13:36:14

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'e0039911-6613-46f2-a475-1e5831734061' User entered 'No (N)'	(b) (4), (b) (6) System	20 Sep 2020 13:36:14
	System	20 Sep 2020 13:36:14

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:36:10', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'e0039911-6613-46f2-a475-1e5831734061' User entered 'None (1)'	(b) (4), (b) (6) System	20 Sep 2020 13:36:14
	System	20 Sep 2020 13:36:14

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:36:12', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'e0039911-6613-46f2-a475-1e5831734061' User entered '20 Sep 2020 09:36'	(b) (4), (b) (6) System	20 Sep 2020 13:36:14
	System	20 Sep 2020 13:36:14

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 7'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:36', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4b8e2147-b37d-4950-941b-367c4031becc' User entered 'None (1)'	(b) (4), (b) (6) System	21 Sep 2020 13:35:47
	System	21 Sep 2020 13:35:47

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:37', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4b8e2147-b37d-4950-941b-367c4031becc' User entered 'No (N)'	System	21 Sep 2020 13:35:47
	System	21 Sep 2020 13:35:47

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:39', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4b8e2147-b37d-4950-941b-367c4031becc' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 13:35:47
	System	21 Sep 2020 13:35:47

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:41', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4b8e2147-b37d-4950-941b-367c4031becc' User entered 'None (1)'	(b) (4), (b) (6) System	21 Sep 2020 13:35:47
	System	21 Sep 2020 13:35:47

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:44', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4b8e2147-b37d-4950-941b-367c4031becc' User entered '21 Sep 2020 09:35'	(b) (4), (b) (6) System	21 Sep 2020 13:35:47
	System	21 Sep 2020 13:35:47

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '14 Sep 2020 16:55'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '14 Sep 2020 19:25'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:03:53', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f39926d2-3cfa-40b5-88e1-9137830fdad7'	(b) (4), (b) (6)	
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Sep 2020 15:05:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:03:57', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f39926d2-3cfa-40b5-88e1-9137830fdad7'	(b) (4), (b) (6)	
	System	15 Sep 2020 15:05:09
User entered 'Some interference with activity (2)'	System	15 Sep 2020 15:05:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:04:01', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f39926d2-3cfa-40b5-88e1-9137830fdad7'	(b) (4), (b) (6)	
	System	15 Sep 2020 15:05:09
User entered 'Some interference with activity (2)'	System	15 Sep 2020 15:05:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:04:04', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f39926d2-3cfa-40b5-88e1-9137830fdad7'	(b) (4), (b) (6)	
	System	15 Sep 2020 15:05:09
User entered 'Some interference with activity (2)'	System	15 Sep 2020 15:05:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:04:18', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f39926d2-3cfa-40b5-88e1-9137830fdad7'	(b) (4), (b) (6)	
	System	15 Sep 2020 15:05:09
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	15 Sep 2020 15:05:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:04:21', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f39926d2-3cfa-40b5-88e1-9137830fdad7'	(b) (4), (b) (6)	
	System	15 Sep 2020 15:05:09
User entered 'Some interference with activity not requiring medical attention (2)'	System	15 Sep 2020 15:05:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:04:24', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f39926d2-3cfa-40b5-88e1-9137830fdad7' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 15:05:09
	System	15 Sep 2020 15:05:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-15T11:04:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f39926d2-3cfa-40b5-88e1-9137830fdad7' User entered '15 Sep 2020 11:04'	(b) (4), (b) (6) System	15 Sep 2020 15:05:09
	System	15 Sep 2020 15:05:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '14 Sep 2020 20:20'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 2'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:19:52', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b2e42809-6e72-4fdd-a882-0b7487a1cb62'	System	16 Sep 2020 15:20:23
User entered 'No interference with activity (1)'	System	16 Sep 2020 15:20:23

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:19:56', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b2e42809-6e72-4fdd-a882-0b7487a1cb62'	(b) (4), (b) (6) System	16 Sep 2020 15:20:23
User entered 'Some interference with activity (2)'	System	16 Sep 2020 15:20:23

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:19:59', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b2e42809-6e72-4fdd-a882-0b7487a1cb62'	(b) (4), (b) (6)	
	System	16 Sep 2020 15:20:23
User entered 'Some interference with activity (2)'	System	16 Sep 2020 15:20:23

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:20:03', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b2e42809-6e72-4fdd-a882-0b7487a1cb62'	(b) (4), (b) (6)	
	System	16 Sep 2020 15:20:23
User entered 'No interference with activity (1)'	System	16 Sep 2020 15:20:23

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:20:07', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b2e42809-6e72-4fdd-a882-0b7487a1cb62' User entered 'None (0)'	System	16 Sep 2020 15:20:23
	System	16 Sep 2020 15:20:23

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:20:10', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b2e42809-6e72-4fdd-a882-0b7487a1cb62' User entered 'None (0)'	System	16 Sep 2020 15:20:23
	System	16 Sep 2020 15:20:23

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:20:15', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b2e42809-6e72-4fdd-a882-0b7487a1cb62'	(b) (4), (b) (6) System	16 Sep 2020 15:20:23
User entered 'No (N)'	System	16 Sep 2020 15:20:23

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-16T11:20:20', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b2e42809-6e72-4fdd-a882-0b7487a1cb62'	(b) (4), (b) (6) System	16 Sep 2020 15:20:23
User entered '16 Sep 2020 11:20'	System	16 Sep 2020 15:20:23

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 3'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:56:41

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 4'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:36:04', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '523f0d51-f8d2-46bf-82cc-84c29adcb7c4' User entered 'None (0)'	System	18 Sep 2020 13:41:09
	System	18 Sep 2020 13:41:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:36:07', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '523f0d51-f8d2-46bf-82cc-84c29adcb7c4'	(b) (4), (b) (6)	
	System	18 Sep 2020 13:41:09
User entered 'No interference with activity (1)'	System	18 Sep 2020 13:41:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:36:10', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '523f0d51-f8d2-46bf-82cc-84c29adcb7c4' User entered 'None (0)'	System	18 Sep 2020 13:41:09
	System	18 Sep 2020 13:41:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:36:15', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '523f0d51-f8d2-46bf-82cc-84c29adcb7c4'	(b) (4), (b) (6)	
	System	18 Sep 2020 13:41:09
User entered 'No interference with activity (1)'	System	18 Sep 2020 13:41:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:40:43', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '523f0d51-f8d2-46bf-82cc-84c29adcb7c4' User entered 'None (0)'	System	18 Sep 2020 13:41:09
	System	18 Sep 2020 13:41:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:40:45', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '523f0d51-f8d2-46bf-82cc-84c29adcb7c4' User entered 'None (0)'	System	18 Sep 2020 13:41:09
	System	18 Sep 2020 13:41:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:40:56', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '523f0d51-f8d2-46bf-82cc-84c29adcb7c4'	(b) (4), (b) (6)	
	System	18 Sep 2020 13:41:09
User entered 'Yes (Y)'	System	18 Sep 2020 13:41:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-18T09:41:02', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '523f0d51-f8d2-46bf-82cc-84c29adcb7c4' User entered '18 Sep 2020 09:41'	(b) (4), (b) (6) System	18 Sep 2020 13:41:09
	System	18 Sep 2020 13:41:09

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 5'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:36:03', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f042686d-0115-49fc-8a76-5827e7eaba97'	(b) (4), (b) (6)	
	System	19 Sep 2020 13:36:22
User entered 'No interference with activity (1)'	System	19 Sep 2020 13:36:22

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:36:05', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f042686d-0115-49fc-8a76-5827e7eaba97'	(b) (4), (b) (6)	
	System	19 Sep 2020 13:36:22
User entered 'No interference with activity (1)'	System	19 Sep 2020 13:36:22

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:36:07', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f042686d-0115-49fc-8a76-5827e7eaba97'	(b) (4), (b) (6)	
	System	19 Sep 2020 13:36:22
User entered 'No interference with activity (1)'	System	19 Sep 2020 13:36:22

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:36:09', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f042686d-0115-49fc-8a76-5827e7eaba97' User entered 'None (0)'	System	19 Sep 2020 13:36:22
	System	19 Sep 2020 13:36:22

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:36:12', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f042686d-0115-49fc-8a76-5827e7eaba97' User entered 'None (0)'	System	19 Sep 2020 13:36:22
	System	19 Sep 2020 13:36:22

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:36:14', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f042686d-0115-49fc-8a76-5827e7eaba97' User entered 'None (0)'	System	19 Sep 2020 13:36:22
	System	19 Sep 2020 13:36:22

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:36:15', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f042686d-0115-49fc-8a76-5827e7eaba97'	(b) (4), (b) (6)	
	System	19 Sep 2020 13:36:22
User entered 'No (N)'	System	19 Sep 2020 13:36:22

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-19T09:36:18', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f042686d-0115-49fc-8a76-5827e7eaba97' User entered '19 Sep 2020 09:36'	(b) (4), (b) (6) System	19 Sep 2020 13:36:22
	System	19 Sep 2020 13:36:22

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 6'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:12', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'fc273096-937c-44cf-a012-8884af1a9ba8'	(b) (4), (b) (6)	
	System	20 Sep 2020 13:35:48
User entered 'No interference with activity (1)'	System	20 Sep 2020 13:35:48

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:16', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'fc273096-937c-44cf-a012-8884af1a9ba8' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 13:35:48
	System	20 Sep 2020 13:35:48

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:19', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'fc273096-937c-44cf-a012-8884af1a9ba8' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 13:35:48
	System	20 Sep 2020 13:35:48

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:20', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'fc273096-937c-44cf-a012-8884af1a9ba8' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 13:35:48
	System	20 Sep 2020 13:35:48

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:21', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'fc273096-937c-44cf-a012-8884af1a9ba8' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 13:35:48
	System	20 Sep 2020 13:35:48

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:23', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'fc273096-937c-44cf-a012-8884af1a9ba8' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 13:35:48
	System	20 Sep 2020 13:35:48

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:43', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'fc273096-937c-44cf-a012-8884af1a9ba8' User entered 'No (N)'	(b) (4), (b) (6) System	20 Sep 2020 13:35:48
	System	20 Sep 2020 13:35:48

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-20T09:35:45', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'fc273096-937c-44cf-a012-8884af1a9ba8' User entered '20 Sep 2020 09:35'	(b) (4), (b) (6) System	20 Sep 2020 13:35:48
	System	20 Sep 2020 13:35:48

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	14 Sep 2020 20:42:19
User entered 'Day 7'	System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:12', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b384f5a4-4bd5-421a-931d-b4fcbdd6c409' User entered 'None (0)'	System	21 Sep 2020 13:35:36
	System	21 Sep 2020 13:35:36

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:14', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b384f5a4-4bd5-421a-931d-b4fcbdd6c409' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 13:35:36
	System	21 Sep 2020 13:35:36

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:15', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b384f5a4-4bd5-421a-931d-b4fcbdd6c409' User entered 'None (0)'	System	21 Sep 2020 13:35:36
	System	21 Sep 2020 13:35:36

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:21', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b384f5a4-4bd5-421a-931d-b4fcbdd6c409' User entered 'None (0)'	System	21 Sep 2020 13:35:36
	System	21 Sep 2020 13:35:36

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:23', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b384f5a4-4bd5-421a-931d-b4fcbdd6c409' User entered 'None (0)'	System	21 Sep 2020 13:35:36
	System	21 Sep 2020 13:35:36

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b384f5a4-4bd5-421a-931d-b4fcbdd6c409' User entered 'None (0)'	System	21 Sep 2020 13:35:36
	System	21 Sep 2020 13:35:36

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:30', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b384f5a4-4bd5-421a-931d-b4fcbdd6c409' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 13:35:36
	System	21 Sep 2020 13:35:36

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-09-21T09:35:33', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b384f5a4-4bd5-421a-931d-b4fcbdd6c409'	(b) (4), (b) (6)	
	System	21 Sep 2020 13:35:36
User entered '21 Sep 2020 09:35'	System	21 Sep 2020 13:35:36

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 20:42:19

US3022167

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:10:36

US3022167

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:10:36

US3022167

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Sep 2020 17:10:36

US3022167

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:10:36

US3022167

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:10:43

US3022167

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6)	21 Sep 2020 17:10:43
	System	

US3022167

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:30:45

US3022167

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '29 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 18:30:45

US3022167

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 18:30:45

US3022167

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 18:30:45

US3022167

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:30:50

US3022167

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6) System	05 Oct 2020 18:30:50

US3022167

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:31:09

US3022167

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '05 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 18:31:09

US3022167

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 18:31:09

US3022167

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 18:31:09

US3022167

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:31:13

US3022167

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 18:31:13

US3022167

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:23:17

US3022167

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '09 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:23:17

US3022167

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Oct 2020 14:23:17

US3022167

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'VISIT3'	(b) (4), (b) (6) System	09 Oct 2020 14:23:17

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '09 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '09:30'	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '09 Oct 2020 09:30'	(b) (4), (b) (6)	
	System	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '37.5' C	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '69'	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'bpm'	(b) (4), (b) (6) System	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '13'	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '102'	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '82'	(b) (4), (b) (6)	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 14:23:50

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	

US3022167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	

US3022167

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:23:58

US3022167

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '09 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:23:58

US3022167

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:24:36

US3022167

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '09 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:24:36

US3022167

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '09:42'	(b) (4), (b) (6)	09 Oct 2020 14:24:36

US3022167

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered '09 Oct 2020 09:42'	(b) (4), (b) (6)	
	System	09 Oct 2020 14:24:36

US3022167

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:24:44

US3022167

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6) System	09 Oct 2020 14:24:44

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 64'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; Nausea/Vomiting/Diarrhea = CHECKED and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; Nausea/Vomiting/Diarrhea = CHECKED and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'CORRECT . MEDICATIONS WERE ADDED TO CM LOG AND AE FOR ACUTE GASTRITIS WAS ADDED' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 06:32:12
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; Nausea/Vomiting/Diarrhea = CHECKED and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 14:52:07
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; Nausea/Vomiting/Diarrhea = CHECKED and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:12', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	System	17 Oct 2020 14:01:50
User entered 'Yes (Y)'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:17', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6) System	17 Oct 2020 14:01:50
User entered 'No (N)'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:29', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6) System	17 Oct 2020 14:01:50
User entered 'Yes (Y)'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '0'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '1'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '1'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:00:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	
	System	17 Oct 2020 14:01:50
User entered '1'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:01:11', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	17 Oct 2020 14:01:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:01:17', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6) System	17 Oct 2020 14:01:50
User entered 'Yes (Y)'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:01:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622'	(b) (4), (b) (6)	17 Oct 2020 14:01:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-17T10:01:41', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4e5282d0-f434-48e4-836b-7b3e14d29622' User entered '17 Oct 2020 10:01:41'	(b) (4), (b) (6) System	17 Oct 2020 14:01:50
	System	17 Oct 2020 14:01:50

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 71'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-27T17:59:17', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3cabf28d-4aae-43b4-8bfc-e7b46228e3b2'	(b) (4), (b) (6)	
	System	27 Oct 2020 21:59:26
User entered 'No (N)'	System	27 Oct 2020 21:59:26

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-27T17:59:22', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3cabf28d-4aae-43b4-8bfc-e7b46228e3b2'	(b) (4), (b) (6)	27 Oct 2020 21:59:26
User entered 'No (N)'	System	27 Oct 2020 21:59:26

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-10-27T17:59:24', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3cabf28d-4aae-43b4-8bfc-e7b46228e3b2' User entered '27 Oct 2020 17:59:24'	(b) (4), (b) (6) System	27 Oct 2020 21:59:26
	System	27 Oct 2020 21:59:26

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 78'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-03T17:44:08', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '5a4a6102-f5e6-4afa-8d4c-fb1eac1cb696'	(b) (4), (b) (6)	
User entered 'No (N)'	System	03 Nov 2020 22:44:16

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-03T17:44:10', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '5a4a6102-f5e6-4afa-8d4c-fb1eac1cb696'	(b) (4), (b) (6)	
	System	03 Nov 2020 22:44:16
User entered 'No (N)'	System	03 Nov 2020 22:44:16

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-03T17:44:13', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '5a4a6102-f5e6-4afa-8d4c-fb1eac1cb696' User entered '03 Nov 2020 17:44:13'	(b) (4), (b) (6) System	03 Nov 2020 22:44:16
	System	03 Nov 2020 22:44:16

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
Data entry locked.	(b) (4), (b) (6)	
	System	17 Aug 2020 23:10:22
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered 'Day 92'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-14T09:08:37', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '9146374f-52d0-4645-9955-822ed00ecf6e'	(b) (4), (b) (6)	
	System	14 Nov 2020 14:08:58
User entered 'No (N)'	System	14 Nov 2020 14:08:58

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-14T09:08:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '9146374f-52d0-4645-9955-822ed00ecf6e'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Nov 2020 14:08:58
	System	14 Nov 2020 14:08:58

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-14T09:08:56', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '9146374f-52d0-4645-9955-822ed00ecf6e' User entered '14 Nov 2020 09:08:56'	(b) (4), (b) (6) System	14 Nov 2020 14:08:58
	System	14 Nov 2020 14:08:58

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 23:10:22

US3022167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Aug 2020 23:10:22
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 23:10:22

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-21T07:20:52', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '60595e3f-aebe-4f4b-b622-b9b55f50d6c3'	System	21 Nov 2020 15:21:01
User entered 'No (N)'	System	21 Nov 2020 15:21:01

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-21T07:20:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '60595e3f-aebe-4f4b-b622-b9b55f50d6c3'	System	21 Nov 2020 15:21:01
User entered 'No (N)'	System	21 Nov 2020 15:21:01

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-21T07:20:57', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '60595e3f-aebe-4f4b-b622-b9b55f50d6c3' User entered '21 Nov 2020 07:20:57'	System	21 Nov 2020 15:21:01
	System	21 Nov 2020 15:21:01

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-27T12:08:32', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a0c66e72-8be6-4bef-bd82-d9b2a3fa3829'	System	27 Nov 2020 17:08:40
User entered 'No (N)'	System	27 Nov 2020 17:08:40

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-27T12:08:35', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a0c66e72-8be6-4bef-bd82-d9b2a3fa3829'	System	27 Nov 2020 17:08:40
User entered 'No (N)'	System	27 Nov 2020 17:08:40

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-11-27T12:08:37', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'a0c66e72-8be6-4bef-bd82-d9b2a3fa3829' User entered '27 Nov 2020 12:08:37'	System	27 Nov 2020 17:08:40
	System	27 Nov 2020 17:08:40

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-02T07:51:37', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4bfcae34-58b7-4e5c-8328-727968d7443e' User entered 'No (N)'	System	02 Dec 2020 12:51:47
	System	02 Dec 2020 12:51:47

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-02T07:51:42', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4bfcae34-58b7-4e5c-8328-727968d7443e' User entered 'No (N)'	System	02 Dec 2020 12:51:47
	System	02 Dec 2020 12:51:47

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-02T07:51:45', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4bfcae34-58b7-4e5c-8328-727968d7443e' User entered '02 Dec 2020 07:51:45'	System	02 Dec 2020 12:51:47
	System	02 Dec 2020 12:51:47

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-09T11:16:01', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '9c6ab58d-3c28-4950-ad7f-621c661af763' User entered 'No (N)'	System	09 Dec 2020 16:16:08
	System	09 Dec 2020 16:16:08

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-09T11:16:03', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '9c6ab58d-3c28-4950-ad7f-621c661af763'	System	09 Dec 2020 16:16:08
User entered 'No (N)'	System	09 Dec 2020 16:16:08

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-09T11:16:05', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '9c6ab58d-3c28-4950-ad7f-621c661af763'	System	09 Dec 2020 16:16:08
User entered '09 Dec 2020 11:16:05'	System	09 Dec 2020 16:16:08

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-16T00:01:11', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '65760c7b-beb8-4a9d-a91c-a318d84fb3d4' User entered 'No (N)'	System	16 Dec 2020 05:01:21
	System	16 Dec 2020 05:01:21

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-16T00:01:14', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '65760c7b-beb8-4a9d-a91c-a318d84fb3d4' User entered 'No (N)'	System	16 Dec 2020 05:01:21
	System	16 Dec 2020 05:01:21

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-16T00:01:16', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '65760c7b-beb8-4a9d-a91c-a318d84fb3d4' User entered '16 Dec 2020 00:01:16'	System	16 Dec 2020 05:01:21
	System	16 Dec 2020 05:01:21

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-23T08:55:14', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '26c9338c-ae3b-4471-9dbd-32c5ce31f779'	System	23 Dec 2020 13:55:24
User entered 'No (N)'	System	23 Dec 2020 13:55:24

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-23T08:55:19', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '26c9338c-ae3b-4471-9dbd-32c5ce31f779' User entered 'No (N)'	System	23 Dec 2020 13:55:24
	System	23 Dec 2020 13:55:24

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-23T08:55:22', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '26c9338c-ae3b-4471-9dbd-32c5ce31f779' User entered '23 Dec 2020 08:55:22'	System	23 Dec 2020 13:55:24
	System	23 Dec 2020 13:55:24

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-30T07:49:48', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '163f67e7-9c2f-4577-b1f1-298bff058e46'	System	30 Dec 2020 12:49:57
User entered 'No (N)'	System	30 Dec 2020 12:49:57

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-30T07:49:51', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '163f67e7-9c2f-4577-b1f1-298bff058e46'	System	30 Dec 2020 12:49:57
User entered 'No (N)'	System	30 Dec 2020 12:49:57

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2020-12-30T07:49:53', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '163f67e7-9c2f-4577-b1f1-298bff058e46'	System	30 Dec 2020 12:49:57
User entered '30 Dec 2020 07:49:53'	System	30 Dec 2020 12:49:57

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-06T00:43:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b725ef12-cfe2-4658-a153-7e8801e778f4'	System	06 Jan 2021 05:44:05
User entered 'No (N)'	System	06 Jan 2021 05:44:05

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-06T00:44:00', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b725ef12-cfe2-4658-a153-7e8801e778f4'	System	06 Jan 2021 05:44:05
User entered 'No (N)'	System	06 Jan 2021 05:44:05

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-06T00:44:02', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b725ef12-cfe2-4658-a153-7e8801e778f4'	System	06 Jan 2021 05:44:05
User entered '06 Jan 2021 00:44:02'	System	06 Jan 2021 05:44:05

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-13T03:05:17', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f28d3278-d60d-4a2e-9fe9-172e460f7e7e'	System	13 Jan 2021 08:05:27
User entered 'No (N)'	System	13 Jan 2021 08:05:27

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-13T03:05:23', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f28d3278-d60d-4a2e-9fe9-172e460f7e7e'	System	13 Jan 2021 08:05:27
User entered 'No (N)'	System	13 Jan 2021 08:05:27

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-13T03:05:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f28d3278-d60d-4a2e-9fe9-172e460f7e7e' User entered '13 Jan 2021 03:05:25'	System	13 Jan 2021 08:05:27

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-20T09:42:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '902f3406-0591-4a91-8b44-aecd7a5d56f8' User entered 'No (N)'	System	20 Jan 2021 14:43:17

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-20T09:43:00', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '902f3406-0591-4a91-8b44-aecd7a5d56f8' User entered 'No (N)'	System	20 Jan 2021 14:43:17

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-20T09:43:07', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '902f3406-0591-4a91-8b44-aecd7a5d56f8' User entered '20 Jan 2021 09:43:07'	System	20 Jan 2021 14:43:17
	System	20 Jan 2021 14:43:17

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-27T04:59:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3e9673cc-f9d0-42ef-bf05-b11333225798'	System	27 Jan 2021 09:59:32
User entered 'No (N)'	System	27 Jan 2021 09:59:32

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-27T04:59:27', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3e9673cc-f9d0-42ef-bf05-b11333225798'	System	27 Jan 2021 09:59:32
User entered 'No (N)'	System	27 Jan 2021 09:59:32

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-01-27T04:59:30', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '3e9673cc-f9d0-42ef-bf05-b11333225798' User entered '27 Jan 2021 04:59:30'	System	27 Jan 2021 09:59:32
	System	27 Jan 2021 09:59:32

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-03T08:01:47', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4776c99b-862e-408e-9c1c-b8b278519d17'	System	03 Feb 2021 13:01:55
User entered 'No (N)'	System	03 Feb 2021 13:01:55

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-03T08:01:49', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4776c99b-862e-408e-9c1c-b8b278519d17'	System	03 Feb 2021 13:01:55
User entered 'No (N)'	System	03 Feb 2021 13:01:55

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-03T08:01:51', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4776c99b-862e-408e-9c1c-b8b278519d17'	System	03 Feb 2021 13:01:55
User entered '03 Feb 2021 08:01:51'	System	03 Feb 2021 13:01:55

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-10T00:41:30', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f6d13c9f-b99e-4e13-8c68-7bea22670163' User entered 'No (N)'	System	10 Feb 2021 05:41:37

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-10T00:41:32', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f6d13c9f-b99e-4e13-8c68-7bea22670163' User entered 'No (N)'	System	10 Feb 2021 05:41:37

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-10T00:41:35', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f6d13c9f-b99e-4e13-8c68-7bea22670163' User entered '10 Feb 2021 00:41:35'	System	10 Feb 2021 05:41:37
	System	10 Feb 2021 05:41:37

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-17T14:18:47', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '075fea64-b3e8-4db6-817c-81f6d7558e75' User entered 'Yes (Y)'	System	17 Feb 2021 19:19:16
	System	17 Feb 2021 19:19:16

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-17T14:18:49', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '075fea64-b3e8-4db6-817c-81f6d7558e75' User entered 'No (N)'	System	17 Feb 2021 19:19:16

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-17T14:18:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '075fea64-b3e8-4db6-817c-81f6d7558e75' User entered 'No (N)'	System	17 Feb 2021 19:19:16
	System	17 Feb 2021 19:19:16

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-17T14:18:59', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '075fea64-b3e8-4db6-817c-81f6d7558e75'	System	17 Feb 2021 19:19:16
User entered 'Yes (Y)'	System	17 Feb 2021 19:19:16

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-17T14:19:01', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '075fea64-b3e8-4db6-817c-81f6d7558e75'	System	17 Feb 2021 19:19:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Feb 2021 19:19:16

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-17T14:19:06', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '075fea64-b3e8-4db6-817c-81f6d7558e75'	System	17 Feb 2021 19:19:16
User entered '17 Feb 2021 14:19:06'	System	17 Feb 2021 19:19:16

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-24T06:09:01', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'e5e27ac7-7f0f-4566-a1e9-5929ba749f35'	System	24 Feb 2021 11:09:09
User entered 'No (N)'	System	24 Feb 2021 11:09:09

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-24T06:09:05', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'e5e27ac7-7f0f-4566-a1e9-5929ba749f35'	System	24 Feb 2021 11:09:09
User entered 'No (N)'	System	24 Feb 2021 11:09:09

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-02-24T06:09:07', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'e5e27ac7-7f0f-4566-a1e9-5929ba749f35' User entered '24 Feb 2021 06:09:07'	System	24 Feb 2021 11:09:09

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-03T11:14:14', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'dc7849b5-077b-43c1-ab88-2d4a47bbd490'	System	03 Mar 2021 16:14:23
User entered 'No (N)'	System	03 Mar 2021 16:14:23

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-03T11:14:16', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'dc7849b5-077b-43c1-ab88-2d4a47bbd490'	System	03 Mar 2021 16:14:23
User entered 'No (N)'	System	03 Mar 2021 16:14:23

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-03T11:14:18', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'dc7849b5-077b-43c1-ab88-2d4a47bbd490'	System	03 Mar 2021 16:14:23
User entered '03 Mar 2021 11:14:18'	System	03 Mar 2021 16:14:23

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-12T12:32:49', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '13f6769d-7c8b-46fa-9516-936bf72c9389' User entered 'No (N)'	System	12 Mar 2021 17:32:57
	System	12 Mar 2021 17:32:57

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-12T12:32:52', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '13f6769d-7c8b-46fa-9516-936bf72c9389' User entered 'No (N)'	System	12 Mar 2021 17:32:57
	System	12 Mar 2021 17:32:57

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-12T12:32:55', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '13f6769d-7c8b-46fa-9516-936bf72c9389' User entered '12 Mar 2021 12:32:55'	System	12 Mar 2021 17:32:57
	System	12 Mar 2021 17:32:57

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-17T06:18:58', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1ca11f21-3a08-42fc-ab07-c51e54d08a60'	System	17 Mar 2021 10:19:28
User entered 'Yes (Y)'	System	17 Mar 2021 10:19:28

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-17T06:19:00', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1ca11f21-3a08-42fc-ab07-c51e54d08a60'	System	17 Mar 2021 10:19:28
User entered 'No (N)'	System	17 Mar 2021 10:19:28

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-17T06:19:05', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1ca11f21-3a08-42fc-ab07-c51e54d08a60'	System	17 Mar 2021 10:19:28
User entered 'No (N)'	System	17 Mar 2021 10:19:28

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-17T06:19:12', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1ca11f21-3a08-42fc-ab07-c51e54d08a60'	System	17 Mar 2021 10:19:28
User entered 'Yes (Y)'	System	17 Mar 2021 10:19:28

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-17T06:19:16', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1ca11f21-3a08-42fc-ab07-c51e54d08a60'	System	17 Mar 2021 10:19:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Mar 2021 10:19:28

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-17T06:19:19', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '1ca11f21-3a08-42fc-ab07-c51e54d08a60'	System	17 Mar 2021 10:19:28
User entered '17 Mar 2021 06:19:19'	System	17 Mar 2021 10:19:28

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-24T07:27:14', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4565352f-d40c-43c0-893b-6beda13a4a96'	System	24 Mar 2021 11:27:39
User entered 'Yes (Y)'	System	24 Mar 2021 11:27:39

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-24T07:27:17', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4565352f-d40c-43c0-893b-6beda13a4a96'	System	24 Mar 2021 11:27:39
User entered 'No (N)'	System	24 Mar 2021 11:27:39

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-24T07:27:20', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4565352f-d40c-43c0-893b-6beda13a4a96'	System	24 Mar 2021 11:27:39
User entered 'No (N)'	System	24 Mar 2021 11:27:39

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-24T07:27:25', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4565352f-d40c-43c0-893b-6beda13a4a96'	System	24 Mar 2021 11:27:39
User entered 'Yes (Y)'	System	24 Mar 2021 11:27:39

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-24T07:27:27', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4565352f-d40c-43c0-893b-6beda13a4a96'	System	24 Mar 2021 11:27:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Mar 2021 11:27:39

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-24T07:27:29', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4565352f-d40c-43c0-893b-6beda13a4a96' User entered '24 Mar 2021 07:27:29'	System	24 Mar 2021 11:27:39
	System	24 Mar 2021 11:27:39

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-31T02:07:17', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4ad93b27-b151-4920-b278-9c42f527903d'	System	31 Mar 2021 06:08:22
User entered 'Yes (Y)'	System	31 Mar 2021 06:08:22

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-31T02:07:36', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4ad93b27-b151-4920-b278-9c42f527903d'	System	31 Mar 2021 06:08:22
User entered 'No (N)'	System	31 Mar 2021 06:08:22

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-31T02:07:48', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4ad93b27-b151-4920-b278-9c42f527903d'	System	31 Mar 2021 06:08:22
User entered 'No (N)'	System	31 Mar 2021 06:08:22

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-31T02:07:59', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4ad93b27-b151-4920-b278-9c42f527903d'	System	31 Mar 2021 06:08:22
User entered 'Yes (Y)'	System	31 Mar 2021 06:08:22

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-31T02:08:06', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4ad93b27-b151-4920-b278-9c42f527903d'	System	31 Mar 2021 06:08:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Mar 2021 06:08:22

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-31T02:08:11', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '4ad93b27-b151-4920-b278-9c42f527903d' User entered '31 Mar 2021 02:08:11'	System	31 Mar 2021 06:08:22
	System	31 Mar 2021 06:08:22

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-07T06:27:41', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b379cf5e-87f2-4d81-bdcc-08ad43a0e224'	System	07 Apr 2021 10:28:05
User entered 'Yes (Y)'	System	07 Apr 2021 10:28:05

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-07T06:27:35', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b379cf5e-87f2-4d81-bdcc-08ad43a0e224'	System	07 Apr 2021 10:28:05
User entered 'No (N)'	System	07 Apr 2021 10:28:05

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-07T06:27:45', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b379cf5e-87f2-4d81-bdcc-08ad43a0e224' User entered 'No (N)'	System	07 Apr 2021 10:28:05
	System	07 Apr 2021 10:28:05

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-07T06:27:49', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b379cf5e-87f2-4d81-bdcc-08ad43a0e224'	System	07 Apr 2021 10:28:05
User entered 'Yes (Y)'	System	07 Apr 2021 10:28:05

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-07T06:27:51', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b379cf5e-87f2-4d81-bdcc-08ad43a0e224'	System	07 Apr 2021 10:28:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 10:28:05

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-07T06:27:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'b379cf5e-87f2-4d81-bdcc-08ad43a0e224' User entered '07 Apr 2021 06:27:54'	System	07 Apr 2021 10:28:05
	System	07 Apr 2021 10:28:05

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-15T01:21:53', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'dde1f4f0-4dca-429b-bb3b-e39bc7c5f58f' User entered 'No (N)'	System	15 Apr 2021 05:21:59
	System	15 Apr 2021 05:21:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-15T01:21:54', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'dde1f4f0-4dca-429b-bb3b-e39bc7c5f58f'	System	15 Apr 2021 05:21:59
User entered 'No (N)'	System	15 Apr 2021 05:21:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-15T01:21:57', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'dde1f4f0-4dca-429b-bb3b-e39bc7c5f58f' User entered '15 Apr 2021 01:21:57'	System	15 Apr 2021 05:21:59
	System	15 Apr 2021 05:21:59

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-21T09:48:06', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0e710008-22e9-4a3c-b58f-8417afe3cb9e' User entered 'No (N)'	System	21 Apr 2021 13:49:21
	System	21 Apr 2021 13:49:21

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-21T09:48:09', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0e710008-22e9-4a3c-b58f-8417afe3cb9e'	System	21 Apr 2021 13:49:21
User entered 'No (N)'	System	21 Apr 2021 13:49:21

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-21T09:49:19', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '0e710008-22e9-4a3c-b58f-8417afe3cb9e' User entered '21 Apr 2021 09:49:19'	System	21 Apr 2021 13:49:21
	System	21 Apr 2021 13:49:21

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-28T10:24:05', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f0d6e445-3800-4a90-b988-8977aebb7154' User entered 'No (N)'	System	28 Apr 2021 21:28:27
	System	28 Apr 2021 21:28:27

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-28T10:24:14', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f0d6e445-3800-4a90-b988-8977aebb7154'	System	28 Apr 2021 21:28:27
User entered 'No (N)'	System	28 Apr 2021 21:28:27

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-04-28T10:24:16', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: 'f0d6e445-3800-4a90-b988-8977aebb7154' User entered '28 Apr 2021 10:24:16'	System	28 Apr 2021 21:28:27

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:50:12

US3022167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:50:12
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:50:12

US3022167

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:46:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:52:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-03T11:14:21', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '8c3b1e90-bcd0-4857-bda9-b4d103190f4b'	System	03 Mar 2021 16:15:15
User entered 'Yes (Y)'	System	03 Mar 2021 16:15:15

US3022167

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:46:53

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:52:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-03T11:14:24', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '8c3b1e90-bcd0-4857-bda9-b4d103190f4b' User entered 'No (N)'	System	03 Mar 2021 16:15:15
	System	03 Mar 2021 16:15:15

US3022167

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:46:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:52:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67391CF3-93E8-4064-981A-995C43A1559B)', Time: '2021-03-03T11:14:26', User OID: 'PatientReportedOutcome (US3022167)', ODM File OID: '8c3b1e90-bcd0-4857-bda9-b4d103190f4b' User entered '03 Mar 2021 11:14:26'	System	03 Mar 2021 16:15:15
	System	03 Mar 2021 16:15:15

US3022167

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 13:49:20

US3022167

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 11:36:35
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'this date is correct' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 13:49:42
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Nov 2020 13:49:20
User entered '13 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 13:49:20

US3022167

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Nov 2020 13:49:20

US3022167

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 13:49:20

US3022167

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 13:49:58

US3022167

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:32:44
User entered 'I'	(b) (4), (b) (6) System	16 Nov 2020 13:49:58

US3022167

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:31:07

US3022167

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:31:07

US3022167

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:31:07

US3022167

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:31:07

US3022167

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:16:00

US3022167

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User entered 'I'	(b) (4), (b) (6) System	04 Jan 2021 16:16:00

US3022167

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:25:03

US3022167

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:25:03

US3022167

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:25:03

US3022167

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:25:03

US3022167

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:25:07

US3022167

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User entered 'I'	(b) (4), (b) (6) System	11 Jan 2021 19:25:07

US3022167

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 19:03:15

US3022167

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:15

US3022167

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:15

US3022167

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:15

US3022167

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:21

US3022167

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:37:52
User entered '1'	(b) (4), (b) (6) System	10 Feb 2021 19:03:21

US3022167

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:59:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 18:44:00

US3022167

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:59:26
	(b) (4)	
User entered '01 Mar 2021'	(b) (4), (b) (6)	01 Mar 2021 18:44:00

US3022167

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:59:26
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Mar 2021 18:44:00

US3022167

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
User entered 'VISIT4'	(b) (4), (b) (6) System	01 Mar 2021 18:44:00

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:36:42

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:36:42

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:36:42

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:36:42

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:36:42
	(b) (4)	

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:36:42

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 10:16:42

US3022167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 10:16:42

US3022167

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:59:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 18:44:11

US3022167

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:59:26
	(b) (4)	
User entered '01 Mar 2021'	(b) (4), (b) (6)	01 Mar 2021 18:44:11

US3022167

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:59:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 18:44:21

US3022167

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:59:26
	(b) (4)	
User entered '01 Mar 2021'	(b) (4), (b) (6)	01 Mar 2021 18:44:21

US3022167

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:59:26
	(b) (4)	
User entered '10:45'	(b) (4), (b) (6)	01 Mar 2021 18:44:21

US3022167

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
User entered '01 Mar 2021 10:45'	(b) (4), (b) (6) System	01 Mar 2021 18:44:21

US3022167

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:59:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 18:44:26

US3022167

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:16:42
User entered 'I'	(b) (4), (b) (6) System	01 Mar 2021 18:44:26

US3022167

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	09 Apr 2021 18:10:35

US3022167

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
User entered '09 Apr 2021'	(b) (4) Chevon Roberts (b) (4)	09 Apr 2021 18:10:35
	(b) (4)	

US3022167

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	09 Apr 2021 18:10:35

US3022167

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
User entered empty.	(b) (4) Chevon Roberts (b) (4)	09 Apr 2021 18:10:35
	(b) (4)	

US3022167

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:45
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	09 Apr 2021 18:10:44

US3022167

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:10:44

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:25
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	09 Dec 2020 17:10:37
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 21 OCT 2020 is reported under Illness Visit Day 1 in PPD Central lab, however, the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit, else clarify. ' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Nov 2020 11:26:10
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 21 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 09:55:50
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 21 OCT 2020 is reported under Illness Visit Day 1 in PPD Central lab, however, the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit, else clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:08:28
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 21 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 11:33:49
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 20:23:02

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:25
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:10:37
User entered '12:00'	(b) (4), (b) (6) (b) (4), (b) (6)	20 Oct 2020 20:23:02

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:25
User entered '19 Oct 2020 12:00'	(b) (4), (b) (6) System	20 Oct 2020 20:23:02

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:25
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:10:37
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	(b) (4), (b) (6) (b) (4), (b) (6)	20 Oct 2020 20:23:02

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:25
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:10:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	20 Oct 2020 20:23:02

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 1 (Day 1)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:30:49
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:43:06
User entered '16 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:42:20
User closed query 'Per CDM: It appears initial symptoms started on 21OCT2020 yet Contact Date is recorded as 19OCT2020. Please reconcile or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 04:49:31
Query 'Per CDM: It appears initial symptoms started on 21OCT2020 yet Contact Date is recorded as 19OCT2020. Please reconcile or clarify' answered with 'CORRECT, SUBECT WAS CALLED ON THE 19OCT2020 AND CAME IN FOR AN ILLNESS VISIT ON 21OCT2020' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 14:53:40
User opened query 'Per CDM: It appears initial symptoms started on 21OCT2020 yet Contact Date is recorded as 19OCT2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 11:28:29
User entered '21 Oct 2020'	Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:30:50
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:30:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered '100'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User entered '%'	(b) (4), (b) (6) System	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:30:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered '36.9' C	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Mild (Mild)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:45:33
	(b) (4)	
User entered 'Mild (Mild)'	Shanice Bennett (b) (4)	03 Nov 2020 21:03:52
	(b) (4)	

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:45:33
	(b) (4)	
User entered 'Mild (Mild)'	Shanice Bennett (b) (4)	03 Nov 2020 21:03:52
	(b) (4)	

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:45:33
User entered 'Mild (Mild)'	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:45:33
User entered 'Mild (Mild)'	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:03:52

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 2 (Day 2)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:31:00
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:43:06
User entered '17 Oct 2020' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:42:20
User entered '23 Oct 2020'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:31:01
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:31:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered '100'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User entered '%'	(b) (4), (b) (6) System	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:31:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered '98.1' F	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Mild (Mild)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Mild (Mild)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Mild (Mild)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Mild (Mild)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:05:17

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Mild (Mild)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:05:17

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 3 (Day 3)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '16 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:43:06
	(b) (4)	
User entered '18 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:42:20
	(b) (4)	
User entered '24 Oct 2020'	Shanice Bennett (b) (4)	03 Nov 2020 21:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered '100'	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User entered '%'	(b) (4), (b) (6) System	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
change Data Entry Error	(b) (4)	
User entered '98.3' F	Shanice Bennett (b) (4)	03 Nov 2020 21:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:06:09

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered 'None (None)'	Shanice Bennett (b) (4)	03 Nov 2020 21:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:06:09

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:06:09

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4)	03 Nov 2020 21:06:09

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:09

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 4 (Day 4)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '17 Oct 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User entered '%'	System	20 Nov 2020 16:49:39
User entered empty.	System	20 Nov 2020 16:43:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
change Data Entry Error	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 5 (Day 5)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '18 Oct 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
change Data Entry Error	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User entered '%'	System	20 Nov 2020 16:49:39
User entered empty.	System	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered missing code ND - Not Done; reason for	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
change Data Entry Error	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:49:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:35

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:35
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 6 (Day 6)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:50

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:39:39
User entered '19 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:39:41
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:50

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:39:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User entered '%'	System	20 Nov 2020 16:49:39
User entered empty.	System	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:39:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:39:47
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:39:48
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:39:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:39:51
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:58:18
	(b) (4), (b) (6)	
User closed query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 16:57:53
	(b) (4), (b) (6)	
Query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' answered with 'changed to none' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:43:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:43:01
User opened query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:40:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	
	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:40:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:58:16
	(b) (4), (b) (6)	
User closed query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 16:57:56
	(b) (4), (b) (6)	
Query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' answered with 'changed to none' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:43:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:43:01
User opened query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:41:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	
	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:41:51
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:42:06
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:42:07
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:42:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:42:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:58:14
	(b) (4), (b) (6)	
User closed query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 16:58:02
	(b) (4), (b) (6)	
Query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' answered with 'changed to none' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:43:21
User opened query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:43:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
	Shanice Bennett (b) (4)	20 Nov 2020 16:43:50
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:58:10
	(b) (4), (b) (6)	
User closed query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 16:58:04
	(b) (4), (b) (6)	
Query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' answered with 'chanhed to noen' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:43:29
User opened query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:43:51
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
	Shanice Bennett (b) (4)	20 Nov 2020 16:43:50
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:58:08
	(b) (4), (b) (6)	
User closed query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 16:58:06
	(b) (4), (b) (6)	
Query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' answered with 'changed to none' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:43:37
User opened query 'Per illness visit source on 19Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
	(b) (4)	
	Shanice Bennett (b) (4)	20 Nov 2020 16:43:50
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:44:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:49:39
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:50

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 7 (Day 7)'	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:03
User entered '20 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:59

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:05
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:43:59

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User entered '%'	System	20 Nov 2020 16:51:04
User entered empty.	System	20 Nov 2020 16:43:59

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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Form: Symptom Log (7)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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Form: Symptom Log (7)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:59
	(b) (4)	

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:59
	(b) (4)	

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:47:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:48:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:48:07
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:48:09
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:48:11
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:48:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:48:26
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:43:59

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:51:04
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:43:59
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 8 (Day 8)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:49:17
User entered '21 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:49:19
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:49:35
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User entered '%'	System	20 Nov 2020 16:53:48
User entered empty.	System	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM: It appears temperature of 36.9 F is rather low. Please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:07:27
Query 'Per CDM: It appears temperature of 36.9 F is rather low. Please review and update accordingly ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:52:46
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 17:52:41
User entered '36.9' C reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:52:41
User opened query 'Per CDM: It appears temperature of 36.9 F is rather low. Please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:36:30
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 17:50:42
User entered '36.9' F reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:51:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:51:37
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:51:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:51:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:51:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:51:53
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:51:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:52:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:52:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:52:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:52:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:52:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per illness visit source on 20Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 16:38:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 16:37:55
Query 'Per illness visit source on 20Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' answered with 'wil update' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:45:02
User opened query 'Per illness visit source on 20Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 17:53:38
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:53:48
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:07

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per illness visit source on 20Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 16:38:37
Query 'Per illness visit source on 20Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' answered with 'will update' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:45:08
User opened query 'Per illness visit source on 20Oct20 (Page 1), this is discrepant. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:54:04
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:54:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:54:19
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:53:48
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:07

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 9 (Day 9)'	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:11
	(b) (4), (b) (6)	
User closed query 'Please mark all items below as "Not Done" since patient was not assessed.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 16:39:05
	(b) (4), (b) (6)	
Query 'Please mark all items below as "Not Done" since patient was not assessed.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:44:03
User opened query 'Please mark all items below as "Not Done" since patient was not assessed.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:56:05
User entered '22 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4)	20 Nov 2020 16:44:18
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:14
	(b) (4), (b) (6)	
User closed query 'Per CDM: Requery: Previous query response on date field is noted as 'updated' however, these have not been updated based on query statement that Assessment was not done. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:52:33
Query 'Per CDM: Requery: Previous query response on date field is noted as 'updated' however, these have not been updated based on query statement that Assessment was not done. Please review and reconcile. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 21:02:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:02:19
User opened query 'Per CDM: Requery: Previous query response on date field is noted as 'updated' however, these have not been updated based on query statement that Assessment was not done. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 19:16:08
User entered '0'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:28
	(b) (4), (b) (6)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	09 Dec 2020 19:43:58
change Data Entry Error		
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User entered '%'	(b) (4), (b) (6)	
	System	09 Dec 2020 19:43:58
User entered empty.	System	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:30
	(b) (4), (b) (6)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	09 Dec 2020 19:43:58
change Data Entry Error		
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:40:04
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:40:06
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:40:08
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:55
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:54
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:52
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:50
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:49
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:47
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:46
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:44
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:43
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:40
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:39
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:37
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:36
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:18

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 10 (Day 10)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:24
User entered '23 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:26
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:28
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User entered '%'	System	07 Dec 2020 18:05:40
User entered empty.	System	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM: It appears temperature of 98.1 C is rather high. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:07:45
Query 'Per CDM: It appears temperature of 98.1 C is rather high. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:53:04
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 17:53:00
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:53:00
User opened query 'Per CDM: It appears temperature of 98.1 C is rather high. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:44:29
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 17:56:30
User entered '98.1' C reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 17:56:37
User entered 'None (None)' reason for change: Data	(b) (4), (b) (6)	
Entry Error	(b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:44:27
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:53
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:57
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:56:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:10
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:05:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:27

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Day 11 (Day 11)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:59:24
User entered '24 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:55
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:50
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User entered '%'	(b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	System	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:24
User entered '98.3' F reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:09
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:06
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:58:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:57
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:56
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:53
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:57:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 18:06:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:44:38

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:03:13
User entered '21 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:03:13
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:03:13
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:03:13
User entered '21 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:03:13
User entered 'Nasal Swab (Nasal Swab)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:03:13
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[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)	29 Apr 2021 21:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:03:13
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:03:13
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:03:13
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:42
User entered '0'	(b) (4), (b) (6) System	03 Nov 2020 21:06:51

US3022167

Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:46:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:52:49
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:04:02
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:06:59

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User accepted default value 'Day 3 (Day 3)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per CDM: Please note that there was no request to leave the Saliva log empty. Kindly update the saliva log lines as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:23:26
Query 'Per CDM: Please note that there was no request to leave the Saliva log empty. Kindly update the saliva log lines as appropriate. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 15:58:54
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 15:58:48
User opened query 'Per CDM: Please note that there was no request to leave the Saliva log empty. Kindly update the saliva log lines as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:25:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 09:38:57
Query 'Data is required. Please complete.' answered with 'PER YOUR REQUEST ' (Site from System).	Shanice Bennett (b) (4)	13 Nov 2020 14:56:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 14:56:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 14:56:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User accepted default value 'Day 5 (Day 5)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 15:59:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 09:39:00
Query 'Data is required. Please complete.' answered with 'PER YOUR REQUEST ' (Site from System).	Shanice Bennett (b) (4)	13 Nov 2020 14:56:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 14:56:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 14:56:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User accepted default value 'Day 7 (Day 7)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 15:59:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 09:39:02
Query 'Data is required. Please complete.' answered with 'PER YOUR REQUEST ' (Site from System).	Shanice Bennett (b) (4)	13 Nov 2020 14:56:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 14:56:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 14:56:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User accepted default value 'Day 9 (Day 9)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 15:59:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 09:39:05
Query 'Data is required. Please complete.' answered with 'PER YOUR REQUEST ' (Site from System).	Shanice Bennett (b) (4)	13 Nov 2020 14:56:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 14:56:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 14:56:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User accepted default value 'Day 14 (Day 14)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 15:59:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 09:39:08
Query 'Data is required. Please complete.' answered with 'PER YOUR REQUEST ' (Site from System).	Shanice Bennett (b) (4)	13 Nov 2020 14:56:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 14:56:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 14:56:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User accepted default value 'Day 21 (Day 21)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 16:00:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 09:39:11
Query 'Data is required. Please complete.' answered with 'PER YOUR REQUEST ' (Site from System).	Shanice Bennett (b) (4)	13 Nov 2020 14:57:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	13 Nov 2020 14:56:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 14:56:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User accepted default value 'Day 28 (Day 28)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	03 Dec 2020 16:00:22
reason for change: Data Entry Error		
User closed query 'Data is required. Please	(b) (4), (b) (6)	17 Nov 2020 09:39:14
complete.' (Site from System).		
Query 'Data is required. Please complete.' answered	Shanice Bennett (b) (4)	13 Nov 2020 14:57:54
with 'PER YOUR REQUEST ' (Site from System).	(b) (4)	
User opened query 'Data is required. Please	System	13 Nov 2020 14:56:04
complete.' (Site from System).		
User entered empty; reason for change Data Entry	Shanice Bennett (b) (4)	13 Nov 2020 14:56:04
Error	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

US3022167

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:32
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	03 Nov 2020 21:10:11
	(b) (4)	

US3022167

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:53:36
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:07:34

US3022167

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '21 Oct 2020'	Shanice Bennett (b) (4)	03 Nov 2020 21:07:34

US3022167

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[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 19:53:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4)	03 Nov 2020 21:07:34

US3022167

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:36
User entered 'SICKD1'	(b) (4), (b) (6) System	03 Nov 2020 21:07:34

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23
	(b) (4)	

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '21 Oct 2020'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '11:16'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User entered '21 Oct 2020 11:16'	(b) (4), (b) (6) System	03 Nov 2020 21:08:23

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	03 Nov 2020 21:08:34
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	03 Nov 2020 21:08:34
User entered '156.7' cm reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:08:34
User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	03 Nov 2020 21:08:23
User entered '103' cm	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:08:23
DataPoint set to visible.	System	03 Nov 2020 21:07:34

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '49.7' kg	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23
	(b) (4)	
DataPoint set to visible.	System	03 Nov 2020 21:07:34

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '36.9' C	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23
	(b) (4)	

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23
	(b) (4)	

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '80'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23
	(b) (4)	

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User entered 'bpm'	(b) (4), (b) (6) System	03 Nov 2020 21:08:23

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '14'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23
	(b) (4)	

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User entered 'breaths/min'	(b) (4), (b) (6) System	03 Nov 2020 21:08:23

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '103'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:23
	(b) (4)	

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User entered 'mmHg'	(b) (4), (b) (6) System	03 Nov 2020 21:08:23

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:53:42
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered '84'	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:08:23

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:53:42
User entered 'mmHg'	(b) (4), (b) (6) System	03 Nov 2020 21:08:23

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:53:42

US3022167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:53:42

US3022167

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:22
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:44
	(b) (4)	

US3022167

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '21 Oct 2020'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:44

US3022167

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:46:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:59

US3022167

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:54:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '21 Oct 2020'	Shanice Bennett (b) (4)	03 Nov 2020 21:08:59

US3022167

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

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:36:05

US3022167

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

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:36:05

US3022167

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

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:36:05

US3022167

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

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	05 Jan 2021 19:36:05

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:36:47

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:33:26
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:57:12

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:36:47

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:33:26
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:57:12

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:36:47

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:36:47

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 12:09:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	05 Jan 2021 19:36:47

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 12:09:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	05 Jan 2021 19:36:47

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:36:47

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User entered empty.	(b) (4), (b) (6) System	05 Jan 2021 19:36:47

US3022167

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User entered empty.	(b) (4), (b) (6) System	05 Jan 2021 19:36:47

US3022167

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:37:16

US3022167

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:37:16

US3022167

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '10:04'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:37:16

US3022167

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User entered '04 Jan 2021 10:04'	(b) (4), (b) (6) System	05 Jan 2021 19:37:16

US3022167

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:37:43

US3022167

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:37:43

US3022167

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '10:18'	(b) (4), (b) (6)	05 Jan 2021 19:37:43

US3022167

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:11
User entered '04 Jan 2021 10:18'	(b) (4), (b) (6) System	05 Jan 2021 19:37:43

US3022167

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:46:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:33
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:10:40
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	24 Aug 2020 23:07:41
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:33:57

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM(requery): Response is noted. However, Adverse event was on 17-Sep-20, the Covid-19 assessment was taken on 19-Oct-20. please update the Covid-19 assessment and all applicable forms completed within this timeframe(17-Sep-20) as appropraite per guidelines, else clarify. Thank you.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:57:19
	(b) (4), (b) (6)	
Query 'Per CDM(requery): Response is noted. However, Adverse event was on 17-Sep-20, the Covid-19 assessment was taken on 19-Oct-20. please update the Covid-19 assessment and all applicable forms completed within this timeframe(17-Sep-20) as appropraite per guidelines, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:23:42
User opened query 'Per CDM(requery): Response is noted. However, Adverse event was on 17-Sep-20, the Covid-19 assessment was taken on 19-Oct-20. please update the Covid-19 assessment and all applicable forms completed within this timeframe(17-Sep-20) as appropraite per guidelines, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 09:12:14
User closed query 'Per CDM, per DM CLR re-query: Response "due to covid" is noted; however, there is no Covid-19 Assessment completed within the timeframe of this AE and no AE recorded for COVID-19. If the subject is COVID positive, please complete all applicable forms, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 09:12:14

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per CDM, per DM CLR re-query: Response "due to covid" is noted; however, there is no Covid-19 Assessment completed within the timeframe of this AE and no AE recorded for COVID-19. If the subject is COVID positive, please complete all applicable forms, else provide clarification. ' answered with 'The only COVID visit that was completed for this subject is already recorded.' (Site from DM).	Morgan Deal (b) (4)	23 Nov 2020 19:16:15
User opened query 'Per CDM, per DM CLR re-query: Response "due to covid" is noted; however, there is no Covid-19 Assessment completed within the timeframe of this AE and no AE recorded for COVID-19. If the subject is COVID positive, please complete all applicable forms, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:32:55
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:32:55
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' answered with 'due to covid' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 22:20:20
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:55:51
User closed query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:30:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4)	03 Nov 2020 21:01:07
User opened query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.	(b) (4), (b) (6)	19 Oct 2020 05:28:56
' (Site from DM).		
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Dysuria, LLT: Dysuria - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:09:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:09:37
Data point term sent to Coder	System	24 Aug 2020 23:08:48
User entered 'DYSURIA'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	17 Sep 2020 00:01:12
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	14 Sep 2020 20:42:19
User entered '18 Aug 2020'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 23:08:34
User entered '08:00' reason for change: Data Entry Error	Shanice Bennett (b) (4)	24 Aug 2020 23:08:34
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 23:08:17
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User entered '18 Aug 2020 08:00'	(b) (4), (b) (6)	
	System	24 Aug 2020 23:08:34
User entered empty.	System	24 Aug 2020 23:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:00:49
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '25 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:00:49
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 21:01:00
User entered '08:00' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:01:00
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 21:00:49
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User entered '25 Aug 2020 08:00'	(b) (4), (b) (6)	
	System	03 Nov 2020 21:01:00
User entered empty.	System	24 Aug 2020 23:08:17

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 23:08:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 23:08:51
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	24 Aug 2020 23:08:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 23:08:17
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 23:08:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 23:08:51
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	24 Aug 2020 23:08:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 23:08:17
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'None (NONE)'	(b) (4) Shanice Bennett (b) (4)	24 Aug 2020 23:08:17

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 22:20:54
User closed query 'Per DM CLR - RQ: Site's response noted. However, please ensure that the field below will be updated (i.e., tick Concomitant Medication field). Please review and update AE eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:50:51
Query 'Per DM CLR - RQ: Site's response noted. However, please ensure that the field below will be updated (i.e., tick Concomitant Medication field). Please review and update AE eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 14:59:11
User opened query 'Per DM CLR - RQ: Site's response noted. However, please ensure that the field below will be updated (i.e., tick Concomitant Medication field). Please review and update AE eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 06:49:22
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 06:49:22
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4)	03 Nov 2020 21:01:19
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 21:04:15
User entered '1'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Per DM CLR - RQ: Site's response on above query noted. However, please confirm why it is correct. Concomitant Medication #4 is recorded that matches this AE during this timeframe. Hence, this ConMed field should be "ticked". Please review and update this field as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:28:50
Query 'Per DM CLR - RQ: Site's response on above query noted. However, please confirm why it is correct. Concomitant Medication #4 is recorded that matches this AE during this timeframe. Hence, this ConMed field should be "ticked". Please review and update this field as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 22:21:01
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 22:20:54
	(b) (4)	
User opened query 'Per DM CLR - RQ: Site's response on above query noted. However, please confirm why it is correct. Concomitant Medication #4 is recorded that matches this AE during this timeframe. Hence, this ConMed field should be "ticked". Please review and update this field as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:59:03
User entered '0'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Shanice Bennett (b) (4)	03 Nov 2020 21:00:49
Data Entry Error	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[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 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	24 Aug 2020 23:08:17
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User entered '0'	(b) (4), (b) (6) System	24 Aug 2020 23:08:51

US3022167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:33:57
User entered '0'	(b) (4), (b) (6) System	24 Aug 2020 23:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:33:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:34:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM(requery): Response is noted. However, Adverse event was on 17-Sep-20, the Covid-19 assessment was taken on 19-Oct-20. please update the Covid-19 assessment and all applicable forms completed within this timeframe(17-Sep-20) as appropriate per guidelines, else clarify. Thank you.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:57:31
	(b) (4), (b) (6)	
Query 'Per CDM(requery): Response is noted. However, Adverse event was on 17-Sep-20, the Covid-19 assessment was taken on 19-Oct-20. please update the Covid-19 assessment and all applicable forms completed within this timeframe(17-Sep-20) as appropriate per guidelines, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:23:25
User opened query 'Per CDM(requery): Response is noted. However, Adverse event was on 17-Sep-20, the Covid-19 assessment was taken on 19-Oct-20. please update the Covid-19 assessment and all applicable forms completed within this timeframe(17-Sep-20) as appropriate per guidelines, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 09:13:16
User closed query 'Per CDM, per DM CLR re-query: Response "due to covid" is noted; however, there is no Covid-19 Assessment completed within the timeframe of this AE and no AE recorded for COVID-19. If the subject is COVID positive, please complete all applicable forms, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 09:13:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per CDM, per DM CLR re-query: Response "due to covid" is noted; however, there is no Covid-19 Assessment completed within the timeframe of this AE and no AE recorded for COVID-19. If the subject is COVID positive, please complete all applicable forms, else provide clarification. ' answered with 'The only COVID visit that was completed for this subject is already recorded.' (Site from DM).	Morgan Deal (b) (4)	23 Nov 2020 19:16:25
User opened query 'Per CDM, per DM CLR re-query: Response "due to covid" is noted; however, there is no Covid-19 Assessment completed within the timeframe of this AE and no AE recorded for COVID-19. If the subject is COVID positive, please complete all applicable forms, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:34:17
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:34:17
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' answered with 'due to covid' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 22:20:31
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:59:56
User closed query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:19:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'NO DATES ARE NOT OVERLAPPING ' (Site from DM).	Shanice Bennett (b) (4)	03 Nov 2020 21:01:42
User opened query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:29:08
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Dysuria, LLT: Dysuria - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 20:21:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 20:21:42
Data point term sent to Coder	System	21 Sep 2020 20:21:22
User entered 'DYSURIA'	(b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '17 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Oct 2020 12:57:25
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	02 Oct 2020 12:57:25
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Sep 2020 20:20:31
User entered '00:00'	(b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User entered empty.	(b) (4), (b) (6)	
	System	02 Oct 2020 12:57:25
User entered '17 Sep 2020 00:00'	System	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	02 Oct 2020 12:57:25
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	02 Oct 2020 12:57:25
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	21 Sep 2020 20:20:31
User entered '00:00'	(b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User entered empty.	(b) (4), (b) (6)	
	System	02 Oct 2020 12:57:25
User entered '19 Sep 2020 00:00'	System	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 12:57:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 12:57:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Stella Yoon (b) (4)	02 Oct 2020 12:57:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 20:20:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 12:57:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 12:57:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Stella Yoon (b) (4)	02 Oct 2020 12:57:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 20:20:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 10:29:38
Query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:02:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:02:15
User opened query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:02:53
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 12:57:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 12:57:25
User entered 'None (NONE)' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	02 Oct 2020 12:57:25
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 20:20:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[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 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User entered '0'	(b) (4), (b) (6) System	21 Sep 2020 20:20:31

US3022167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:05
User entered '0'	(b) (4), (b) (6) System	21 Sep 2020 20:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:34:05

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:34:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal infection, LLT: Yeast infection - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 15:00:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 15:00:11
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 14:58:45
User entered 'yeast infection'	(b) (4), (b) (6)	10 Nov 2020 14:57:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '05 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '08 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:43:31
Query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 22:23:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 22:22:46
User opened query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:00:49
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Nov 2020 14:57:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Nov 2020 14:57:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[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 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User entered '0'	(b) (4), (b) (6) System	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:14
User entered '1'	(b) (4), (b) (6) System	10 Nov 2020 14:57:46

US3022167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:34:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:07:34

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Please confirm spelling.' (Site from CRA).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 16:36:23
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 16:36:21
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Acute gastritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 19:09:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 19:09:03
Data point term sent to Coder	System	09 Dec 2020 19:08:12
Query 'Please confirm spelling.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:08:07
Coding entries removed.	(b) (4), (b) (6)	09 Dec 2020 19:08:02
User entered 'ACUTE GASTRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:08:02
User opened query 'Please confirm spelling.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 18:09:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Acute gastritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:55:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:55:46
Data point term sent to Coder	System	10 Nov 2020 15:14:12
User entered 'acute gastritis'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:36:25
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:36:27
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:36:28
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:36:30
	(b) (4), (b) (6)	
User entered '14 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:36:32
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:36:33
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:09:58
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'this is ongoing' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 18:46:42
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 03:06:37
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:36:35
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:36:37
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08
	(b) (4)	

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:36:38
	(b) (4), (b) (6)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08
	(b) (4)	

US3022167

Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' canceled (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:14:54
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:57:57
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:36:40
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the hospital admission date. ' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4)	25 Mar 2021 14:15:02
User opened query 'PV Query: Please provide the hospital admission date. ' (Site from Safety).	(b) (4), (b) (6) (b) (4)	25 Mar 2021 13:54:53
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:02:36
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Related (NOT RELATED)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Related (NOT RELATED)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM). Query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:43:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 22:23:30
User opened query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4)	19 Nov 2020 22:23:25
User entered 'None (NONE)'	(b) (4), (b) (6)	18 Nov 2020 10:00:57
	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08

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Folder: Adverse Events

Form: Adverse Events (8)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '1'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

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Folder: Adverse Events

Form: Adverse Events (8)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' canceled (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:15:19
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. ' canceled (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:15:11
Query 'PV Query: Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event. ' canceled (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:15:08
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:03:07
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)	25 Mar 2021 14:00:42
User opened query 'PV Query: Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:57:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 15:14:08

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 10:45:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 10:45:57
User closed query 'Per CDM: Subject had negative test so possible COVID-19 Infection has been ruled out. Per eCCGs "If illness sample was negative, an alternative diagnosis should be determined and recorded as an AE. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome".)' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 08:51:31
Data point term sent to Coder	System	12 Feb 2021 18:24:33
Query 'Per CDM: Subject had negative test so possible COVID-19 Infection has been ruled out. Per eCCGs "If illness sample was negative, an alternative diagnosis should be determined and recorded as an AE. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome".)' answered with 'updated in both edc and chart' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 18:23:59
Coding entries removed.	(b) (4), (b) (6)	12 Feb 2021 18:23:46
User entered 'Covid like-illness' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 18:23:46
User opened query 'Per CDM: Subject had negative test so possible COVID-19 Infection has been ruled out. Per eCCGs "If illness sample was negative, an alternative diagnosis should be determined and recorded as an AE. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome".)' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 20:22:25

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[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per CDM, re-query: Site response noted; however "Possible Covid-19 Infection" does not reflect a final diagnosis. To satisfy previous query, please update the AE term to a more specific diagnosis, else clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 20:22:25
Query 'Per CDM, re-query: Site response noted; however "Possible Covid-19 Infection" does not reflect a final diagnosis. To satisfy previous query, please update the AE term to a more specific diagnosis, else clarify. ' answered with 'subject was negative. what does this need to be changed to?' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:20:25
User opened query 'Per CDM, re-query: Site response noted; however "Possible Covid-19 Infection" does not reflect a final diagnosis. To satisfy previous query, please update the AE term to a more specific diagnosis, else clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 12:28:15
User closed query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:08:27
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 13:30:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 13:30:30
Data point term sent to Coder	System	30 Dec 2020 13:29:30
Query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term ' answered with 'UPDATED TO "POSSIBLE COVID-19 INFECTION"' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 13:29:20
Coding entries removed.	(b) (4), (b) (6)	30 Dec 2020 13:29:05
User entered 'POSSIBLE COVID-19 INFECTION' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 13:29:05
User opened query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 11:48:18

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EAB) (1725)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:52:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:52:52
Data point term sent to Coder	System	07 Dec 2020 21:39:25
User entered 'possible covid infection'	(b) (4), (b) (6) (b) (4)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:38:36

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '24 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 21:38:36

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 22:36:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 22:36:06
Data point term sent to Coder	System	18 Feb 2021 22:35:21
User entered 'ANXIETY'	(b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Feb 2021 22:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 23:34:34

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	25 Mar 2021 23:04:57
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 16:43:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 16:43:34
Data point term sent to Coder	System	19 Mar 2021 16:42:15
User entered 'Dehydration'	(b) (4), (b) (6) (b) (4)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '14 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User entered empty.	(b) (4), (b) (6) System	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 14:21:32
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 23:32:47
User entered empty.	System	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

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Folder: Adverse Events

Form: Adverse Events (11)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:38:53
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:05:49
Signature has been broken.		01 Apr 2021 13:05:34
User entered 'Not Applicable (NOT APPLICABLE) reason for change: Data Entry Error		01 Apr 2021 13:05:34
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Mar 2021 08:06:21
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'None (NONE)'	(b) (4), (b) (6)	19 Mar 2021 16:41:21

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Folder: Adverse Events

Form: Adverse Events (11)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

US3022167

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 17:09:28
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'waiting on medical records to arrive ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:51:43
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 23:32:15
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	25 Mar 2021 23:04:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	19 Mar 2021 16:41:21

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:04:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:41:21

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Folder: Adverse Events

Form: Adverse Events (11)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 17:09:39
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:09:36
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)	13 Apr 2021 17:09:32
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments.' answered with 'waiting on medical records to arrive ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:51:54
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'waiting on medical records to arrive ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:51:51
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 'waiting on medical records to arrive ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:51:47
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 23:34:11

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (11)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 23:33:43
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), (b) (6) (b) (4), (b) (6)	02 Apr 2021 23:33:20
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	25 Mar 2021 23:04:57
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:41:21

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User entered '0'	(b) (4), (b) (6) System	19 Mar 2021 16:41:21

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:57:05
User entered 'I'	(b) (4), (b) (6) System	19 Mar 2021 16:41:21

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 16:57:05

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:34:21

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
	(b) (4)	
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 13:15:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 13:15:40
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 13:13:54
User entered 'cholecystitis'	(b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User entered empty.	(b) (4), (b) (6) System	05 Apr 2021 13:13:40

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:13:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 13:13:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:13:49
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:13:40
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

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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 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User entered empty.	(b) (4), (b) (6) System	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User closed query 'Per MM: Please confirm this event did not meet seriousness criteria else update, as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 06:55:02
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Query 'Per MM: Please confirm this event did not meet seriousness criteria else update, as appropriate. ' answered with 'did not require seriousness criteria standards ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 18:54:13
User opened query 'Per MM: Please confirm this event did not meet seriousness criteria else update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:22:50
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

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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 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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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 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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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 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[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 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User entered '0'	(b) (4), (b) (6) System	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:21
User entered '1'	(b) (4), (b) (6) System	05 Apr 2021 13:13:40

US3022167

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:34:21

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:03:03
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:18
User entered	System	09 Apr 2021 14:11:53
'USA-US051-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	09 Apr 2021 14:11:53
Un-reviewed for Safety.		09 Apr 2021 14:11:53
User entered 'New' reason for change: Data Entry Error		09 Apr 2021 13:18:41
Reviewed for Safety.		09 Apr 2021 13:18:38
User entered		09 Apr 2021 13:18:38
'USA-US051-2020-mRNA-1273-P301000005'		

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:03:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 20:58:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 20:58:56
Data point term sent to Coder	System	08 Apr 2021 20:57:29
User entered 'Dehydration'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:03:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:03:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:03:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:03:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '19 Mar 2021'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:15
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '22 Mar 2021'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:29
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	
	System	08 Apr 2021 20:57:24
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	08 Apr 2021 20:57:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	08 Apr 2021 20:57:24
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	08 Apr 2021 20:57:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 20:57:24
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Apr 2021 20:57:01
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
	(b) (4)	
User entered '19 Mar 2021'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:58
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:05:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:05:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:05:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:05:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:05:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:05:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 20:57:01

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 20:01:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 20:01:03
Data point term sent to Coder	System	12 Apr 2021 18:50:37
User entered 'allergic rhinitis'	(b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 18:49:44

US3022167

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 18:49:44

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:33
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Mar 2021 14:02:21
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'This was a mistake in e-diary' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 15:04:58
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 10:17:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per CDM, re-query: Please refer to a log line as there is no medication recorded for 17,18, 20 Aug, else update to record the medication taken as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:13:37
Query 'Per CDM, re-query: Please refer to a log line as there is no medication recorded for 17,18, 20 Aug, else update to record the medication taken as appropriate or clarify. ' answered with 'MEDICATIONS ARE RECORDED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:57:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User opened query 'Per CDM, re-query: Please refer to a log line as there is no medication recorded for 17,18, 20 Aug, else update to record the medication taken as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:09:42
User closed query 'Per CDM, re-query: Please note that there is no corresponding medication that matches the information on Diary Dose 1, Day 1,2 and 4 (17,18,20 Aug). Kindly update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:09:42
Query 'Per CDM, re-query: Please note that there is no corresponding medication that matches the information on Diary Dose 1, Day 1,2 and 4 (17,18,20 Aug). Kindly update as appropriate or clarify.' answered with 'medication updated for dysuria' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 22:24:48
User opened query 'Per CDM, re-query: Please note that there is no corresponding medication that matches the information on Diary Dose 1, Day 1,2 and 4 (17,18,20 Aug). Kindly update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:28:21
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, 2, & 4, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or interferes with 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)	17 Nov 2020 09:28:21
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with 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)	17 Nov 2020 09:26:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with 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 'updated' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 12:30:00
Query 'Per DM CLR: Per Diary Dose 1 Day 1, 2, & 4, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or interferes with 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 'updated' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 12:28:00
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with 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)	06 Nov 2020 11:49:14
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, 2, & 4, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or interferes with 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)	06 Nov 2020 11:49:07
Query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with 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.' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:49:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:46:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with 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 Oct 2020 04:43:06
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:46:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 07:37:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 07:37:38
Data point term sent to Coder Coding entries removed.	System Stella Yoon (b) (4)	02 Oct 2020 18:15:40 02 Oct 2020 18:14:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 00:42:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 00:42:21
Data point term sent to Coder User entered 'IBUPROFEN'	System Chevon Roberts (b) (4)	17 Aug 2020 23:47:34 17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per DM CLR: Please update the indication to reflect the location of SCIATIC NERVE PAIN (e.g right or left). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 18:22:40
Query 'Per DM CLR: Please update the indication to reflect the location of SCIATIC NERVE PAIN (e.g right or left). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	02 Oct 2020 18:14:51
User entered 'left leg SCIATIC NERVE PAIN' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	02 Oct 2020 18:14:44
User opened query 'Per DM CLR: Please update the indication to reflect the location of SCIATIC NERVE PAIN (e.g right or left). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 14:46:02
User entered 'SCIATIC NERVE PAIN'	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:46:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '200'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'mg (mg)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'as needed (PRN)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Oral (ORAL)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of LEFT LEG SCIATIC NERVE PAIN. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 11:27:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of LEFT LEG SCIATIC NERVE PAIN. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:00:03
User entered 'UN UNK 2015' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 20:59:54
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of LEFT LEG SCIATIC NERVE PAIN. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 16:52:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 14:28:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'CORRECT' (Site from System).	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:46:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 23:46:41
User entered 'UN UNK 2010'	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:46:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:46:41

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: CLARITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 00:12:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 00:12:44
Data point term sent to Coder	System	17 Aug 2020 23:47:35
User entered 'CLARITHROMYCIN'	Chevon Roberts (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'H-PYLORI'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '125'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'mg (mg)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'as needed (PRN)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26
	(b) (4)	

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Oral (ORAL)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'CORRECT' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 14:28:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Chevon Roberts (b) (4)	17 Aug 2020 23:47:31
User entered 'UN UNK 2017'	(b) (4)	
	System	17 Aug 2020 23:47:26
	Chevon Roberts (b) (4)	17 Aug 2020 23:47:26
	(b) (4)	

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per DM CLR: Please review and verify if this medication is ongoing as this is not the standard duration of treatment for this medication. Either update the Stop Date or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 09:08:43
Query 'Per DM CLR: Please review and verify if this medication is ongoing as this is not the standard duration of treatment for this medication. Either update the Stop Date or provide explanation for continued use. Update eCRF as appropriate. ' answered with 'this is still ongoing' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:04:23
User opened query 'Per DM CLR: Please review and verify if this medication is ongoing as this is not the standard duration of treatment for this medication. Either update the Stop Date or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:06:02
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26
	(b) (4)	

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:47:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Aug 2020 09:55:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Aug 2020 09:55:51
Data point term sent to Coder	System	17 Aug 2020 23:48:35
User entered 'ETONOGESTREL'	Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per DM CLR: Indication = CONTRACEPTION. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 09:09:03
' (Site from DM).		
Query 'Per DM CLR: Indication = CONTRACEPTION. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	10 Nov 2020 15:04:45
' answered with 'updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 15:04:39
User opened query 'Per DM CLR: Indication = CONTRACEPTION. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	06 Nov 2020 10:04:33
' (Site from DM).		
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'CONTRACEPTION'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '68'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'mg (mg)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'once daily (QD)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Other (OTHER)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'IMPLANT'	(b) (4) Chevon Roberts (b) (4) (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'CORRECT' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 14:28:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Chevon Roberts (b) (4)	17 Aug 2020 23:48:31
User entered '24 Apr 2019'	(b) (4)	
	System	17 Aug 2020 23:48:26
	Chevon Roberts (b) (4)	17 Aug 2020 23:48:26
	(b) (4)	

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 23:48:26

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 01:06:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 01:06:45
	(b) (4)	
Data point term sent to Coder	System	21 Sep 2020 20:24:32
User entered 'FLUCONAZOLE'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:29:20
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4)	03 Nov 2020 21:10:40
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 05:37:12
User entered 'DYSURIA'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '150'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
User entered '1'	(b) (4), (b) (6) System	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
User entered '1'	(b) (4), (b) (6) System	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:01
User entered '804 (804)'	(b) (4), (b) (6) System	21 Sep 2020 20:24:31

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 01:06:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 01:06:45
	(b) (4)	
Data point term sent to Coder	System	21 Sep 2020 20:25:34
User entered 'FLUCONAZOLE'	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'DYSURIA'	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '150'	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
User entered '1'	(b) (4), (b) (6) System	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
User entered '1'	(b) (4), (b) (6) System	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:04
User entered '804 (804)'	(b) (4), (b) (6) System	21 Sep 2020 20:25:17

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
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)	13 Nov 2020 12:44:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 12:44:44
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 12:30:18
Data point term sent to Coder	System	13 Nov 2020 12:28:18
Coding entries removed.	Shanice Bennett (b) (4)	13 Nov 2020 12:27:44
	(b) (4)	
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)	10 Nov 2020 15:01:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 15:01:35
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 15:00:52
User entered 'acetaminophen'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'PAIN AT INJECTION SITE/Headache' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 12:29:49
	(b) (4)	
User entered 'Pain at injection site' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 12:27:44
	(b) (4)	
User entered 'muscle aches'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '500'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Shanice Bennett (b) (4)	13 Nov 2020 12:29:49
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '18 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 12:27:44
	(b) (4)	
User entered '16 Sep 2020'	(b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
User entered '2'	(b) (4), (b) (6)	
	System	13 Nov 2020 12:29:49
User entered '1'	System	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
User entered '1'	(b) (4), (b) (6) System	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:08
User entered '804 (804)'	(b) (4), (b) (6) System	10 Nov 2020 15:00:49

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE, PRODUCTSYNONYM: DIFLUCAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 15:02:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 15:02:34
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 15:01:55
User entered 'Diflucan'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'yeast infection'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '150'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
User entered '1'	(b) (4), (b) (6) System	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
User entered '1'	(b) (4), (b) (6) System	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:26
User entered '804 (804)'	(b) (4), (b) (6) System	10 Nov 2020 15:01:30

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:55:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:55:51
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 15:02:55
User entered 'promethazine'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 18:58:41
Query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.' answered with 'this is for ae' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 18:59:49
User opened query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:58:56
User entered 'vomiting'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '25'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '26 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:52:30
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 15:02:08

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 17:13:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 17:13:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:58:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:58:47
Data point term sent to Coder	System	10 Nov 2020 15:03:58
User entered 'ondansetron'	(b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'acute gastritis'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '4'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 15:02:58

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
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: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:53:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:53:44
Data point term sent to Coder	System	10 Nov 2020 15:03:58
User entered 'sucralfate'	(b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'acute gastritis'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:05:04
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).	(b) (4)	10 Nov 2020 15:05:04
User opened query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		10 Nov 2020 15:03:51
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 15:03:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 22:36:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 22:36:59
Data point term sent to Coder	System	18 Feb 2021 22:36:23
User entered 'CITALOPRAM'	(b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'ANXIETY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '10'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Feb 2021 22:35:22

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:20:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:20:17
Data point term sent to Coder	System	05 Apr 2021 13:18:58
User entered 'hydrocodone/acetaminophen'	(b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'cholecystectomy'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '5/325'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:18:45

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:23:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:23:26
Data point term sent to Coder	System	05 Apr 2021 13:21:00
User entered 'lorazepam'	(b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'anxiety'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 13:20:16

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 14:40:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 14:40:25
Data point term sent to Coder	System	05 Apr 2021 13:22:01
User entered 'pantoprazole'	(b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'acute gastritis'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '40'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 13:21:28

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 19:55:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 19:55:46
Data point term sent to Coder	System	12 Apr 2021 18:47:02
User entered 'clonazepam'	(b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'anxiety'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0.5'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'as directed'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:46:51

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 19:57:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 19:57:28
Data point term sent to Coder	System	12 Apr 2021 18:48:19
User entered 'cetirizine'	(b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'allergic rhinitis'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '10'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 18:47:53

US3022167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:46:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:33
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 13:14:03
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:14:03
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Sep 2020 21:58:12
	(b) (4)	

US3022167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:46:53

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:14:44

US3022167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:46:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'cholecystectomy'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:14:44

US3022167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:14:44

US3022167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:46:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:14:44

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered		
'USA-US051-2020-MRNA-1273-P301000005'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Paul'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Bradley'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '340 Eisenhower Dr.'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Savannah'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'GA'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '31406'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:43:29
User entered 'US'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 14:04:13
User entered '3'	System	09 Apr 2021 13:22:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '2'	System	05 Oct 2020 13:43:41
User entered '1'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered		
'USA-US051-2020-MRNA-1273-P301000005'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Paul'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Bradley'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '340 Eisenhower Dr.'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Savannah'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'GA'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '31406'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:43:29
User entered 'US'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 14:04:13
User entered '3'	System	09 Apr 2021 13:22:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '2'	System	05 Oct 2020 13:43:41
User entered '1'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:46:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:06:37
User entered '22/Sep/2020 10:24'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:46:53

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.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:43:29
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered		
'USA-US051-2020-MRNA-1273-P301000005'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Paul'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Bradley'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '340 Eisenhower Dr.'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Savannah'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'GA'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '31406'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:43:29
User entered 'US'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 14:04:13
User entered '3'	System	09 Apr 2021 13:22:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '2'	System	05 Oct 2020 13:43:41
User entered '1'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:46:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:06:37
User entered '05/Oct/2020 13:43'	System	05 Oct 2020 13:43:41

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:46:53

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)	09 Apr 2021 13:21:33
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 13:43:41

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered		
'USA-US051-2020-MRNA-1273-P301000005'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Paul'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Bradley'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '340 Eisenhower Dr.'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Savannah'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'GA'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '31406'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:43:29
User entered 'US'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 14:04:13
User entered '3'	System	09 Apr 2021 13:22:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '2'	System	05 Oct 2020 13:43:41
User entered '1'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:46:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '09/Apr/2021 06:22'	(b) (4) System	09 Apr 2021 13:22:26

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:46:53

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)	20 Apr 2021 16:20:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 13:22:26

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered		
'USA-US051-2020-MRNA-1273-P301000005'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:19:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:21:33
Un-reviewed for Safety.	System	09 Apr 2021 13:18:38
DataPoint Un-verified.	System	09 Apr 2021 13:18:38
Signature has been broken.	System	09 Apr 2021 13:18:38
User entered 'Yes (Y)'	System	09 Apr 2021 13:18:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'No (N)'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Paul'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Bradley'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '340 Eisenhower Dr.'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'Savannah'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered 'GA'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:24:30
User entered '31406'	System	22 Sep 2020 14:24:10

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:06:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:43:29
User entered 'US'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 14:04:13
User entered '3'	System	09 Apr 2021 13:22:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:02:36
	(b) (4)	
User entered '2'	System	05 Oct 2020 13:43:41
User entered '1'	System	22 Sep 2020 14:24:37

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:46:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '09/Apr/2021 07:04'	(b) (4) System	09 Apr 2021 14:04:13

US3022167

Folder: SAE USA-US051-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:46:53

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)	20 Apr 2021 16:20:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 14:04:13

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'USA-US051-2021-MRNA-1273-P301000007'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Yes (Y)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Yes (Y)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Paul'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Bradley'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered '340 Eisenhower Dr.'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Savannah'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'GA'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered '31406'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'US'	(b) (4) System	09 Apr 2021 14:12:51

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:12:51

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'USA-US051-2021-MRNA-1273-P301000007'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Yes (Y)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Yes (Y)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'No (N)'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Paul'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Bradley'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered '340 Eisenhower Dr.'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'Savannah'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered 'GA'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:12:44
User entered '31406'	System	09 Apr 2021 14:11:53

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'US'	(b) (4) System	09 Apr 2021 14:12:51

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:12:51

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:46:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered '09/Apr/2021 07:12'	(b) (4) System	09 Apr 2021 14:12:51

US3022167

Folder: SAE USA-US051-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:46:53

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)	20 Apr 2021 20:08:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:17:37
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 14:12:51