

US3022065 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:52:39

All time stamps listed in this document are displayed in GMT

US3022065

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

Participant ID

US3022065

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

US3022065

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 15:46:24

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Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 15:46:24

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Date of Informed Consent (*dd MMM yyyy*) 29 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input 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 15:46:24

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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 15:46:24

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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 15:46:24

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
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 15:46:24

Generated On: 09 Jun 2021 14:52:39

Condition	GASTROESPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3022065

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Condition	ALLERGY TO CODEINE
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Condition	OSTEOARTHRITIS IN LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Condition	OSTEOARTHRITIS IN LEFT HIP
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Condition	ALLERGY TO IBUPROFEN
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3022065

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 08:12
Height (xxx.x)	169 cm
Weight (xxx.x)	93.5 kg
BMI (xxx.x)	32.73695 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 15:46:24

Generated On: 09 Jun 2021 14:52:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 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 15:46:24

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Date of assessment (*dd MMM yyyy*) 29 JUL 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*) UN UNK 1994

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 15:46:24

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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 15:46:24

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:35

Generated On: 09 Jun 2021 14:52:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 100141

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 15:46:35

Generated On: 09 Jun 2021 14:52:39

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 15:46:35

Generated On: 09 Jun 2021 14:52:39

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)	29 JUL 2020
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 08:12
Temperature (xxx.x)	36.8 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 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 15:46:35

Generated On: 09 Jun 2021 14:52:39

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)	29 JUL 2020
Time of assessment (00:00-23:59)	10:13 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 10:13
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

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) 29 JUL 2020

What was the treatment time? (00:00-23:59) 09:41 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 09:41

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 15:46:24

Generated On: 09 Jun 2021 14:52:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JUL 2020

Collection time (00:00-23:59)

08:39 (24 HR)

Collection date and time (derived)

29 JUL 2020 08:39

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:37	29 JUL 2020 08:37
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

29 JUL 2020 10:20

PC Open Date & Time

29 JUL 2020 10:01

PC Close Date & Time

29 JUL 2020 12:31

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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 96.1 °F

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

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

PC Time Stamp	29 JUL 2020 20:17
PC Open Date & Time	29 JUL 2020 13:26
PC Close Date & Time	30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

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

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 20:19

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 06:12

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 02:45

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

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

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 21:22

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 05:14

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

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

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 03:48

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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

29 JUL 2020 10:21

PC Open Date & Time

29 JUL 2020 10:01

PC Close Date & Time

29 JUL 2020 12:31

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

29 JUL 2020 20:17

PC Open Date & Time

29 JUL 2020 13:26

PC Close Date & Time

30 JUL 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

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

30 JUL 2020 20:20

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

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

01 AUG 2020 06:13

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

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

02 AUG 2020 02:46

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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

02 AUG 2020 21:22

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

04 AUG 2020 05:14

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

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

05 AUG 2020 03:49

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 10:22
PC Open Date & Time	29 JUL 2020 10:01
PC Close Date & Time	29 JUL 2020 12:31

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 20:18
PC Open Date & Time	29 JUL 2020 13:26
PC Close Date & Time	30 JUL 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

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 ☒

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 20:20
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

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 ☒

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 06:14
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

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 ☒

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 02:47
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 21:23
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 05:15
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2315

EAB) (1725)

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 03:49
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3022065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

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)	2 SEP 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:58
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 16:35
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3022065

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 16:04 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 16:04

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

US3022065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	08:44 (24 HR)
Collection date and time (derived)	2 SEP 2020 08:44

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:12	2 SEP 2020 09:12
Nasopharyngeal Swab 2	No		

US3022065

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 16:31

PC Open Date & Time

02 SEP 2020 16:24

PC Close Date & Time

02 SEP 2020 18:54

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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	02 SEP 2020 20:56
PC Open Date & Time	02 SEP 2020 19:49
PC Close Date & Time	03 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:07

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

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

97.6 °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

05 SEP 2020 06:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 21:31

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 05:36

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

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

07 SEP 2020 17:17

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 20:21

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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

02 SEP 2020 16:32

PC Open Date & Time

02 SEP 2020 16:24

PC Close Date & Time

02 SEP 2020 18:54

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

02 SEP 2020 20:56

PC Open Date & Time

02 SEP 2020 19:49

PC Close Date & Time

03 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

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

03 SEP 2020 20:08

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

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

05 SEP 2020 06:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

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

05 SEP 2020 21:32

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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

07 SEP 2020 05:37

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

07 SEP 2020 17:17

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

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

08 SEP 2020 20:21

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 16:33
PC Open Date & Time	02 SEP 2020 16:24
PC Close Date & Time	02 SEP 2020 18:54

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 20:57
PC Open Date & Time	02 SEP 2020 19:49
PC Close Date & Time	03 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

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 ☒

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:09
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 06:22
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

100 of 2315

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:32
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

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 ☒

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 05:37
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 17:18
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

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 ☒

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:22
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3022065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	VISIT3

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:00
Temperature (xxx.x)	37.1 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)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3022065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	11:06 (24 HR)
Collection date and time (derived)	30 SEP 2020 11:06

US3022065

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 OCT 2020 14:24:50

Patient Cloud Open Date & Time

28 SEP 2020 00:01

Patient Cloud Close Date & Time

02 OCT 2020 23:59

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 <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"/>

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 <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"/>

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 OCT 2020 17:41:55
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	05 NOV 2020 18:15:28
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 106
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"/>

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 113
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"/>

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 <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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

15 DEC 2020 16:27:57

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

20 DEC 2020 13:08:27

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

25 DEC 2020 04:47:36

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 159

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

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

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

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

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

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

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

19 JAN 2021 08:31:10

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 17:45:50
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 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	31 JAN 2021 19:42:57
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 08:45:09
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

16 FEB 2021 16:22:34

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

22 FEB 2021 05:40:48

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 09:52:41
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 18:14:12
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 08:01:23

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 16:30:27

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

29 MAR 2021 11:50:25

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

06 APR 2021 19:01:30

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 07:24:34

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Date and time of submission

26 APR 2021 12:42:30

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Date and time of submission

03 MAY 2021 12:57:59

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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°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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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°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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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°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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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°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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐
Yes ☐

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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°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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	30 NOV 2021 23:59
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US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 523

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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="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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
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Patient Cloud Close Date & Time	06 SEP 2022 23:59
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US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 ☐

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3022065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:52:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 09:52:54

US3022065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 23:01:39

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3022065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	16:14 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 16:14
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022065

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3022065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 22:56:00

Generated On: 09 Jun 2021 14:52:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 FEB 2021

Collection time (00:00-23:59)

16:51 (24 HR)

Collection date and time (derived)

16 FEB 2021 16:51

US3022065

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:36

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

Date of Contact	26 OCT 2020
Time of Contact	11:00
Date and Time of Contact (derived)	26 OCT 2020 11:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input checked="" type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

	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	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

Date	25 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

Date	26 OCT 2020
------	-------------

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

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

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

Temperature	36.8 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 type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>

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

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	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 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input 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"/>

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

	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	
Assessment Not Done	
O2 Saturation	
O2 Saturation Units	
Temperature	

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

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

Shortness of Breath	None	<input 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"/>

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

	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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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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"/>

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

Date of Visit	26 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	26 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

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 11:25
Height (xxx.x)	169 cm
Weight (xxx.x)	93.7 kg
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3022065

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 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3022065

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

Visit date (dd MMM yyyy)	22 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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US3022065

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Date of updated informed consent (<i>dd MMM yyyy</i>)	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3022065

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

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

US3022065

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	09:54 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 09:54
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3022065

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 10:56
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3022065

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3022065

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

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

Treatment Date and Time (derived) 22 JAN 2021 10:26

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

What was the frequency of the study treatment dosing? ONCE

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

US3022065

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

09:20 (24 HR)

Collection date and time (derived)

22 JAN 2021 09:20

US3022065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	09:24
Collection Date and Time (derived)	22 JAN 2021 09:24

US3022065

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:24

Generated On: 09 Jun 2021 14:52:39

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

US3022065

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	16:14 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 16:14
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	17:59 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 17:59
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3022065

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3022065

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 16 FEB 2021

What was the treatment time? (00:00-23:59) 17:29 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 17:29

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

What was the frequency of the study treatment dosing? ONCE

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

US3022065

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:23

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:56:00

Generated On: 09 Jun 2021 14:52:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022065

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:56:00

Generated On: 09 Jun 2021 14:52:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 23:01:39

Generated On: 09 Jun 2021 14:52:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 23:01:39

Generated On: 09 Jun 2021 14:52:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:20 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 09:20
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 23:01:39

Generated On: 09 Jun 2021 14:52:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 23:01:39

Generated On: 09 Jun 2021 14:52:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	09:37 (24 HR)
Collection date and time (derived)	15 MAR 2021 09:37

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

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) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

AEID

Adverse event

ACUTE SINUSITIS

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)

26 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)

09 NOV 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 (1)

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

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)	_____

US3022065

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

AEID

Adverse event

RIGHT ANTERIOR CERVICAL
CHAIN LYMPHADENOPATHY

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)

26 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)

09 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

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

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

AEID	
Adverse event	POSSIBLE COVID INFECTION
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)	22 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)	09 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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 22:12:48

Generated On: 09 Jun 2021 14:52:39

	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 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 (2)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Name of Medication INDAPOMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 1.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

	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 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GATROESOPHAGEAL REFLUX
DISEAS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 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 (7)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Name of Medication SULFAMETHOXAZOLE/TRIMETHOPRIM

Prophylaxis Yes ☐
No ☒

Indication ACUTE SINUSITIS

Dose per administration 800/160

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 (7)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 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)	09 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POSSIBLE COVID INFECTION

Dose per administration 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

EVERY 4 HOURS

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 22:12:48

Generated On: 09 Jun 2021 14:52:39

	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 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Name of Medication BENZONATATE

Prophylaxis Yes ☐
No ☒

Indication POSSIBLE COVID INFECTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 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)		09 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Name of Medication ALBUTEROL INHALED

Prophylaxis Yes ☐
No ☒

Indication POSSIBLE COVID-19 INFECTION

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		09 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

Name of Medication METHYL PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication POSSIBLE COVID-19 INFECTION

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

AS DIRECTED

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

PRODUCTION RELEASE (v12.003

396 of 2315

EAB) (1725)

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 22:12:48

Generated On: 09 Jun 2021 14:52:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 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)		09 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3022065

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 15:46:22

Generated On: 09 Jun 2021 14:52:39

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:52:39

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:52:39

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3022065 (Prod: Meridian Clinical Research-Savannah)

US3022065

Form: Participant Creation

Generated On: 09 Jun 2021 14:52:39

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:11:28
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'US3022065'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 12:09:24
	(b) (4)	

US3022065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:30:42
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 13:48:57
	(b) (4)	

US3022065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:30:42
	(b) (4), (b) (6)	
User closed query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	29 Jul 2020 14:04:52
Query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	29 Jul 2020 14:04:52
User opened query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	29 Jul 2020 13:50:38
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 12:09:25

US3022065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[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 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:30:42
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4)	29 Jul 2020 13:48:57
	(b) (4)	

US3022065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'SCRN'	(b) (4), (b) (6) System	29 Jul 2020 13:48:57

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered (b) (6) 1958'	RWS_ENDPOINT	29 Jul 2020 12:09:26
	ENDPOINT (b) (4)	
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered '61'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'YEARS'	(b) (4), (b) (6) System	29 Jul 2020 13:49:15

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '61'	(b) (4), (b) (6) System	29 Jul 2020 13:49:38

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered 'Female (F)'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered 'I'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:14
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:15
	(b) (4)	

US3022065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 17:23:11
	(b) (4), (b) (6)	
DataPoint Un-verified.	Stella Yoon (b) (4)	24 Aug 2020 21:26:54
	(b) (4)	
User entered '29 Jul 2020' reason for change: Data Entry Error	Stella Yoon (b) (4)	24 Aug 2020 21:26:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:23
	(b) (4), (b) (6)	
User entered '28 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:38
	(b) (4)	

US3022065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'Jul 2020'	(b) (4), (b) (6) System	29 Jul 2020 13:49:38

US3022065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '2020'	(b) (4), (b) (6) System	29 Jul 2020 13:49:38

US3022065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:23
	(b) (4), (b) (6)	
User entered 'Amendment 1 (1)'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:38
	(b) (4)	

US3022065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:38
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:23
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 13:49:38
	(b) (4)	

US3022065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:23
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 13:49:38
	(b) (4)	

US3022065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:23
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 13:49:38
	(b) (4)	

US3022065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:23
	(b) (4), (b) (6)	
User entered empty.	RWS_ENDPOINT	29 Jul 2020 12:09:25
	ENDPOINT (b) (4)	
	(b) (4)	

US3022065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'I'	(b) (4), (b) (6) System	29 Jul 2020 13:50:04

US3022065

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:29
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 13:50:04
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:52:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:31:42
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:32:21
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User closed query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	06 Oct 2020 19:25:19
Query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' answered with 'con med log updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 12:45:29
User opened query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:28:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:36:23
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:25
Data point term sent to Coder	System	29 Jul 2020 14:32:42
User entered 'Hypertension'	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:32:33

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'un UNK 2019'	Morgan Deal (b) (4)	29 Jul 2020 14:32:33
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:32:33
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:32:33
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:32:33
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:32:33
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'Jan 2019'	(b) (4), (b) (6) System	29 Jul 2020 14:32:33

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '2019'	(b) (4), (b) (6) System	29 Jul 2020 14:32:33

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:32:33

US3022065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:32:33

US3022065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:38
	(b) (4)	
Data point term sent to Coder	System	29 Jul 2020 14:33:44
User entered 'Gastroesophageal reflux disease'	Morgan Deal (b) (4)	29 Jul 2020 14:33:04
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'un UNK 2019'	Morgan Deal (b) (4)	29 Jul 2020 14:33:04
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:33:04
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:33:04
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:33:04
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:33:04
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'Jan 2019'	(b) (4), (b) (6) System	29 Jul 2020 14:33:04

US3022065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '2019'	(b) (4), (b) (6) System	29 Jul 2020 14:33:04

US3022065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:33:04

US3022065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:33:04

US3022065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:33
	(b) (4)	
Data point term sent to Coder	System	29 Jul 2020 14:33:44
User entered 'Allergy to codeine'	Morgan Deal (b) (4)	29 Jul 2020 14:33:18
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'un UNK 1980'	Morgan Deal (b) (4)	29 Jul 2020 14:33:18
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:33:18
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:33:18
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:33:18
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:33:18
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'Jan 1980'	(b) (4), (b) (6) System	29 Jul 2020 14:33:18

US3022065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '1980'	(b) (4), (b) (6) System	29 Jul 2020 14:33:18

US3022065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:33:18

US3022065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:33:18

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:23:30
User closed query 'Per DM CLR: Please review Condition and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, Gout, etc.) Please update and if applicable reconcile with AE/CM eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 14:21:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:08:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:08:47
Data point term sent to Coder	System	02 Sep 2020 18:08:23
Query 'Per DM CLR: Please review Condition and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, Gout, etc.) Please update and if applicable reconcile with AE/CM eCRF so there would be an appropriate match. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 18:08:12
DataPoint Un-verified.	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 18:08:08
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 18:08:08
User entered 'osteoARTHRITIS IN LEFT KNEE' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 18:08:08
User opened query 'Per DM CLR: Please review Condition and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, Gout, etc.) Please update and if applicable reconcile with AE/CM eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:28:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:36:23

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 23:52:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 23:52:04
Data point term sent to Coder	System	29 Jul 2020 14:33:44
User entered 'Arthritis in left knee'	Morgan Deal (b) (4)	29 Jul 2020 14:33:34
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'un UNK 1994'	Morgan Deal (b) (4)	29 Jul 2020 14:33:34
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:33:34
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:33:34
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:33:34
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:33:34
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'Jan 1994'	(b) (4), (b) (6) System	29 Jul 2020 14:33:34

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '1994'	(b) (4), (b) (6) System	29 Jul 2020 14:33:34

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:33:34

US3022065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:33:34

US3022065

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:23:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:36:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:36:42
User closed query 'Per DM CLR: Please review Condition and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, Gout, etc.) Please update and if applicable reconcile with AE/CM eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 14:22:09
Query 'Per DM CLR: Please review Condition and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, Gout, etc.) Please update and if applicable reconcile with AE/CM eCRF so there would be an appropriate match. Otherwise, clarify. ' answered with 'done' (Site from DM).	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 18:08:25
Data point term sent to Coder	System	02 Sep 2020 18:08:23
DataPoint Un-verified.	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 18:08:21
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 18:08:21
User entered 'osteoARTHRITIS IN LEFT HIP' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 18:08:21
User opened query 'Per DM CLR: Please review Condition and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, Gout, etc.) Please update and if applicable reconcile with AE/CM eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:28:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:36:23

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 23:52:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 23:52:04
Data point term sent to Coder	System	29 Jul 2020 14:34:45
User entered 'Arthritis in left hip'	Morgan Deal (b) (4)	29 Jul 2020 14:33:47
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'un UNK 1994'	Morgan Deal (b) (4)	29 Jul 2020 14:33:47
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:33:47
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:33:47
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:33:47
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:33:47
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'Jan 1994'	(b) (4), (b) (6) System	29 Jul 2020 14:33:47

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '1994'	(b) (4), (b) (6) System	29 Jul 2020 14:33:47

US3022065

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:33:47

US3022065

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:33:47

US3022065

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:22
	(b) (4)	
Data point term sent to Coder	System	29 Jul 2020 14:34:47
User entered 'Allergy to Ibuprofen'	Morgan Deal (b) (4)	29 Jul 2020 14:34:10
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'un UNK 2000'	Morgan Deal (b) (4)	29 Jul 2020 14:34:10
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:34:10
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:34:10
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:34:10
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:34:10
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'Jan 2000'	(b) (4), (b) (6) System	29 Jul 2020 14:34:10

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '2000'	(b) (4), (b) (6) System	29 Jul 2020 14:34:10

US3022065

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:34:10

US3022065

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:34:10

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
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: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:38
	(b) (4)	
Data point term sent to Coder	System	29 Jul 2020 14:34:45
User entered 'Allergy to Penicillin'	Morgan Deal (b) (4)	29 Jul 2020 14:34:25
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'un UNK 1960'	Morgan Deal (b) (4)	29 Jul 2020 14:34:25
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:34:25
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:34:25
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:34:25
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:36:23
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:34:25
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'Jan 1960'	(b) (4), (b) (6) System	29 Jul 2020 14:34:25

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '1960'	(b) (4), (b) (6) System	29 Jul 2020 14:34:25

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:34:25

US3022065

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:34:25

US3022065

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 17:23:30
	(b) (4), (b) (6)	
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:52:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:52:15
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 17:30:50
User entered 'POST MENOPAUSAL'	Shanice Bennett (b) (4)	26 Aug 2020 17:29:57
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 17:23:30
	(b) (4), (b) (6)	
User entered 'UN UNK 1994'	Shanice Bennett (b) (4)	26 Aug 2020 17:29:57
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 17:23:30
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	26 Aug 2020 17:29:57
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 17:23:30
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	26 Aug 2020 17:29:57
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 17:23:30
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	26 Aug 2020 17:29:57
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 17:23:30
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	26 Aug 2020 17:29:57
	(b) (4)	

US3022065

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'Jan 1994'	(b) (4), (b) (6) System	26 Aug 2020 17:29:57

US3022065

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '1994'	(b) (4), (b) (6) System	26 Aug 2020 17:29:57

US3022065

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 17:29:57

US3022065

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 17:29:57

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered '29 Jul 2020'	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered '08:12'	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered '29 Jul 2020 08:12'	(b) (4), (b) (6) System	29 Jul 2020 14:35:09

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered '169' cm	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	
DataPoint set to visible.	System	29 Jul 2020 13:50:04

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered '93.5' kg	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	
DataPoint set to visible.	System	29 Jul 2020 13:50:04

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
Amendment Manager: User entered '32.73695'	(b) (4), (b) (6)	
User entered '32.7'	System	16 Sep 2020 23:37:52
DataPoint set to visible.	System	29 Jul 2020 14:35:09
	System	29 Jul 2020 13:50:04

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	29 Jul 2020 14:35:09
DataPoint set to visible.	System	29 Jul 2020 13:50:04

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:02:21
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) (b) (4), (b) (6)	04 Nov 2020 08:57:47
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) (b) (4)	03 Nov 2020 15:27:17
DataPoint Un-verified.	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:10
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:10
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) (b) (4), (b) (6)	21 Oct 2020 13:07:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:35:33
User entered '36.8' C	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:35:09

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:02:23
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:02:25
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
	(b) (4)	
User entered missing code ND - Not Done; reason for	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
change Per Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered '68'	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'bpm'	(b) (4), (b) (6) System	29 Jul 2020 14:35:09

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:02:26
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
	(b) (4)	
User entered missing code ND - Not Done; reason for	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
change Per Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered '16'	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'breaths/min'	(b) (4), (b) (6) System	29 Jul 2020 14:35:09

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:02:31
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered '134'	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'mmHg'	(b) (4), (b) (6) System	29 Jul 2020 14:35:09

US3022065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:02:32
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
	(b) (4)	
User entered missing code ND - Not Done; reason for	Morgan Deal (b) (4)	03 Nov 2020 15:27:10
change Per Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:35:33
	(b) (4), (b) (6)	
User entered '76'	Morgan Deal (b) (4)	29 Jul 2020 14:35:09
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User entered 'mmHg'	(b) (4), (b) (6) System	29 Jul 2020 14:35:09

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:09:02

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:09:02

US3022065

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:37:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	29 Jul 2020 14:35:19
	(b) (4)	

US3022065

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:58:39
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 20:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:37:02
	(b) (4), (b) (6)	
User entered '29 Jul 2020'	Morgan Deal (b) (4)	29 Jul 2020 14:35:19
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	(b) (4) System	24 Aug 2020 21:26:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:34:43
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	29 Jul 2020 14:35:46
User entered '29 Jul 2020'	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:35:46

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:39

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:43
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 14:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 14:36:02
User entered 'No (N)' reason for change: Data Entry Error	Morgan Deal (b) (4)	29 Jul 2020 14:36:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 14:35:46
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:35:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:39

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	31 Aug 2020 09:12:32
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:30:02
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 12:19:55
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:34:43
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:35:46

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:39

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:43
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:35:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:43
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:35:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:39

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:43
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:35:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:43
	(b) (4), (b) (6)	
User entered 'un UNK 1994'	Morgan Deal (b) (4)	29 Jul 2020 14:35:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:39

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:43
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:35:46
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:34:56
User entered 'No (N)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:23

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered 'No (N)'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:34:56
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:23

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:34:56
User entered 'No (N)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:23

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

[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 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered 'No (N)'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

[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 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:34:56
User entered 'No (N)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:23

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:34:56
User entered 'No (N)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:23

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

[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 13:09:02
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered 'No (N)'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

[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 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered 'No (N)'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:34:56
User entered 'No (N)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:23

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:34:56
User entered 'No (N)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:23

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered 'No (N)'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered empty.	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:34:56
User entered '0'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:23

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

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 13:09:02
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered '0'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered 'I'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'I'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:34:56
	(b) (4), (b) (6)	
User entered 'Ongoing person to person transmission'	Morgan Deal (b) (4)	29 Jul 2020 14:37:23
	(b) (4)	

US3022065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:37:48
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:33

US3022065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:37:48
User entered '29 Jul 2020'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:33

US3022065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:37:48
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:37:33

US3022065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'VISIT1'	(b) (4), (b) (6) System	29 Jul 2020 14:37:33

US3022065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:34
User closed query 'The Randomization Date is not equal to first dose of study drug on the Exposure Form. Please review and reconcile.' (Site from System).	(b) (4), (b) (6) System	29 Jul 2020 14:04:52
Query 'The Randomization Date is not equal to first dose of study drug on the Exposure Form. Please review and reconcile.' answered by data change (Site from System).	System	29 Jul 2020 14:04:52
User opened query 'The Randomization Date is not equal to first dose of study drug on the Exposure Form. Please review and reconcile.' (Site from System).	System	29 Jul 2020 13:50:38
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 12:49:49

US3022065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:39

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:12:13
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:12:13
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:39:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 12:49:49
User entered '100141' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 12:49:49

US3022065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:39

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:34
User entered '>=18 and <65 years and not at risk (1)'	(b) (4), (b) (6) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 12:49:49

US3022065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:39

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:16:37
User closed query 'Complete page to confirm that the subject was assigned to the correct cohort.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Sep 2020 13:37:13
Query 'Complete page to confirm that the subject was assigned to the correct cohort.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:43:54
User entered 'No (N)'	Shanice Bennett (b) (4)	22 Aug 2020 01:43:47
User opened query 'Complete page to confirm that the subject was assigned to the correct cohort.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Aug 2020 00:06:07

US3022065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:39

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:16:37
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:43:47

US3022065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:39

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:16:37
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:43:47

US3022065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:16:37
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:43:47

US3022065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:16:37
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:43:47

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:11
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) (b) (4), (b) (6)	04 Nov 2020 08:57:23
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) (b) (4)	03 Nov 2020 15:27:49
DataPoint Un-verified.	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
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) (b) (4), (b) (6)	20 Oct 2020 10:50:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '169' cm	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:12
DataPoint Un-verified.	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '93.5' kg	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:11
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) (b) (4), (b) (6)	04 Nov 2020 08:57:23
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) (b) (4)	03 Nov 2020 15:27:49
DataPoint Un-verified.	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
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) (b) (4), (b) (6)	20 Oct 2020 10:50:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '169' cm	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:12
DataPoint Un-verified.	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '93.5' kg	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Deal (b) (4)	29 Jul 2020 14:38:46
	(b) (4)	

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '29 Jul 2020'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '08:12'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered '29 Jul 2020 08:12'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '36.8' C	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered 'Oral (Oral)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered empty.	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '68'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'bpm'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '16'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'breaths/min'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '134'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'mmHg'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '76'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'mmHg'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:11
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) (b) (4), (b) (6)	04 Nov 2020 08:57:23
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) (b) (4)	03 Nov 2020 15:27:49
DataPoint Un-verified.	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
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) (b) (4), (b) (6)	20 Oct 2020 10:50:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '169' cm	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:12
DataPoint Un-verified.	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:27:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '93.5' kg	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '29 Jul 2020'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
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) (b) (4), (b) (6)	05 Aug 2020 16:26:45
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Time is correct' (Site from System).	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:55
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).		29 Jul 2020 14:38:46
User entered '10:13'	Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered '29 Jul 2020 10:13'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '36.8' C	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered 'Oral (Oral)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered empty.	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '61'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'bpm'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '15'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'breaths/min'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '134'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'mmHg'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:39:45
User entered '80'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:38:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'mmHg'	(b) (4), (b) (6) System	29 Jul 2020 14:38:46

US3022065

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:40:44
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:02

US3022065

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:40:44
User entered '29 Jul 2020'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:02

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:40:59
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:40:59
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:40:59
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:40:59
User closed query 'Start Date is prior to the Date of Randomization. Please review and provide any needed correction.' (Site from System).	(b) (4), (b) (6) System	29 Jul 2020 14:04:52
User entered '29 Jul 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 14:04:52
User opened query 'Start Date is prior to the Date of Randomization. Please review and provide any needed correction.' (Site from System).	System	29 Jul 2020 13:50:38
User entered '28 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:40:59
User entered '09:41'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
	(b) (4), (b) (6)	
User entered '29 Jul 2020 09:41'	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 09:41'	System	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:40:59
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 15:40:59
User entered 'ONCE'	(b) (4), (b) (6) System	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	29 Jul 2020 13:50:38

US3022065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:41:07
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:22

US3022065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:41:07
User entered '29 Jul 2020'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:22

US3022065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:41:07
User entered '08:39'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:22

US3022065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered '29 Jul 2020 08:39'	(b) (4), (b) (6) System	29 Jul 2020 14:39:22

US3022065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:52:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:41:13
User entered '29 Jul 2020'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:38

US3022065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Deal (b) (4)	29 Jul 2020 14:39:38
	(b) (4)	

US3022065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:41:13
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:38

US3022065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:41:13
User entered '08:37'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:38

US3022065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered '29 Jul 2020 08:37'	(b) (4), (b) (6) System	29 Jul 2020 14:39:38

US3022065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Deal (b) (4)	29 Jul 2020 14:39:38
	(b) (4)	

US3022065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:41:13
User entered 'No (N)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:38

US3022065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:41:13
User entered empty.	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:38

US3022065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered empty.	(b) (4), (b) (6) System	29 Jul 2020 14:39:38

US3022065

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:41:24
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	29 Jul 2020 14:39:45

US3022065

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered '1'	(b) (4), (b) (6) System	29 Jul 2020 14:39:45

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:19:46', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '568fd6b7-9225-4b7e-8259-1c266fec003a'	(b) (4), (b) (6) System	29 Jul 2020 14:20:14
User entered 'Yes (Y)'	System	29 Jul 2020 14:20:14

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:19:52', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '568fd6b7-9225-4b7e-8259-1c266fec003a'	(b) (4), (b) (6)	
User entered '98.2'	System	29 Jul 2020 14:20:14

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:20:04', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '568fd6b7-9225-4b7e-8259-1c266fec003a'	(b) (4), (b) (6) System	29 Jul 2020 14:20:14
User entered 'No (N)'	System	29 Jul 2020 14:20:14

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:20:11', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '568fd6b7-9225-4b7e-8259-1c266fec003a'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:20:14
User entered '29 Jul 2020 10:20'	System	29 Jul 2020 14:20:14

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '29 Jul 2020 10:01'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 10:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '29 Jul 2020 12:31'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 12:31'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:16:36', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f3826d01-6763-46b2-909e-f872f85c82a0'	(b) (4), (b) (6)	
	System	30 Jul 2020 00:17:11
User entered 'Yes (Y)'	System	30 Jul 2020 00:17:11

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:16:48', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f3826d01-6763-46b2-909e-f872f85c82a0'	(b) (4), (b) (6) System	30 Jul 2020 00:17:11
User entered '96.1'	System	30 Jul 2020 00:17:11

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:16:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f3826d01-6763-46b2-909e-f872f85c82a0'	(b) (4), (b) (6) System	30 Jul 2020 00:17:11
User entered 'No (N)'	System	30 Jul 2020 00:17:11

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:17:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f3826d01-6763-46b2-909e-f872f85c82a0'	(b) (4), (b) (6) System	30 Jul 2020 00:17:11
User entered '29 Jul 2020 20:17'	System	30 Jul 2020 00:17:11

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '29 Jul 2020 13:26'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 13:26'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '30 Jul 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '29 Jul 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 2'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:18:58', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0a5ebd93-f0eb-478c-897e-e394782c5be9'	(b) (4), (b) (6)	
	System	31 Jul 2020 00:19:20
User entered 'Yes (Y)'	System	31 Jul 2020 00:19:20

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:19:04', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0a5ebd93-f0eb-478c-897e-e394782c5be9'	(b) (4), (b) (6)	
User entered '95.9'	System	31 Jul 2020 00:19:20

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:19:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0a5ebd93-f0eb-478c-897e-e394782c5be9'	(b) (4), (b) (6) System	31 Jul 2020 00:19:20
User entered 'No (N)'	System	31 Jul 2020 00:19:20

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:19:16', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0a5ebd93-f0eb-478c-897e-e394782c5be9'	(b) (4), (b) (6)	
	System	31 Jul 2020 00:19:20
User entered '30 Jul 2020 20:19'	System	31 Jul 2020 00:19:20

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '30 Jul 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '29 Jul 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '31 Jul 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 3'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:12:34', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9f96245-fd7c-4c7b-afa5-d045380a1171'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	01 Aug 2020 10:13:02

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:12:44', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9f96245-fd7c-4c7b-afa5-d045380a1171'	(b) (4), (b) (6)	
User entered '98.1'	System	01 Aug 2020 10:13:02

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:12:51', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9f96245-fd7c-4c7b-afa5-d045380a1171'	(b) (4), (b) (6)	
	System	01 Aug 2020 10:13:02
User entered 'No (N)'	System	01 Aug 2020 10:13:02

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:12:56', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9f96245-fd7c-4c7b-afa5-d045380a1171'	(b) (4), (b) (6)	
	System	01 Aug 2020 10:13:02
User entered '01 Aug 2020 06:12'	System	01 Aug 2020 10:13:02

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '31 Jul 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '01 Aug 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 4'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:45:38', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0c64133a-a870-46a1-bb56-4d93cae08ba3'	(b) (4), (b) (6)	
	System	02 Aug 2020 06:46:05
User entered 'Yes (Y)'	System	02 Aug 2020 06:46:05

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:45:44', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0c64133a-a870-46a1-bb56-4d93cae08ba3'	(b) (4), (b) (6)	02 Aug 2020 06:46:05
User entered '97.1'	System	02 Aug 2020 06:46:05

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:45:52', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0c64133a-a870-46a1-bb56-4d93cae08ba3'	(b) (4), (b) (6)	02 Aug 2020 06:46:05
User entered 'No (N)'	System	02 Aug 2020 06:46:05

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:45:59', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0c64133a-a870-46a1-bb56-4d93cae08ba3'	(b) (4), (b) (6) System	02 Aug 2020 06:46:05
User entered '02 Aug 2020 02:45'	System	02 Aug 2020 06:46:05

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '01 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Aug 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 5'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:13', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '64e223a4-0610-45f4-8af9-80c7c564e717'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	03 Aug 2020 01:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:18', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '64e223a4-0610-45f4-8af9-80c7c564e717'	(b) (4), (b) (6)	
User entered '96.1'	System	03 Aug 2020 01:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '64e223a4-0610-45f4-8af9-80c7c564e717'	(b) (4), (b) (6)	
	System	03 Aug 2020 01:22:29
User entered 'No (N)'	System	03 Aug 2020 01:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:26', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '64e223a4-0610-45f4-8af9-80c7c564e717'	(b) (4), (b) (6)	
User entered '02 Aug 2020 21:22'	System	03 Aug 2020 01:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 14:04:52
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 6'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:21', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e7c96b8b-8fcb-4aff-a9bc-9dcb8aad9fa2'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	04 Aug 2020 09:14:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:28', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e7c96b8b-8fcb-4aff-a9bc-9dcb8aad9fa2'	(b) (4), (b) (6)	
User entered '97.1'	System	04 Aug 2020 09:14:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:32', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e7c96b8b-8fcb-4aff-a9bc-9dcb8aad9fa2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Aug 2020 09:14:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:36', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e7c96b8b-8fcb-4aff-a9bc-9dcb8aad9fa2'	(b) (4), (b) (6) System	04 Aug 2020 09:14:38
User entered '04 Aug 2020 05:14'	System	04 Aug 2020 09:14:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 14:04:52
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 7'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:48:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1adbf91e-d41d-46ba-950d-7d181e3235a3'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	05 Aug 2020 07:48:42

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:48:30', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1adbf91e-d41d-46ba-950d-7d181e3235a3'	(b) (4), (b) (6)	
User entered '96.1'	System	05 Aug 2020 07:48:42

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:48:34', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1adbf91e-d41d-46ba-950d-7d181e3235a3'	(b) (4), (b) (6)	
	System	05 Aug 2020 07:48:42
User entered 'No (N)'	System	05 Aug 2020 07:48:42

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:48:39', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1adbf91e-d41d-46ba-950d-7d181e3235a3'	(b) (4), (b) (6)	
User entered '05 Aug 2020 03:48'	System	05 Aug 2020 07:48:42

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '05 Aug 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:20:52', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f5876e0f-fe03-4e4d-a5ae-a646f3c379bb'	(b) (4), (b) (6) System	29 Jul 2020 14:21:33
User entered 'None (1)'	System	29 Jul 2020 14:21:33

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:20:58', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f5876e0f-fe03-4e4d-a5ae-a646f3c379bb'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:21:33
User entered 'No (N)'	System	29 Jul 2020 14:21:33

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:21:02', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f5876e0f-fe03-4e4d-a5ae-a646f3c379bb'	(b) (4), (b) (6) System	29 Jul 2020 14:21:33
User entered 'No (N)'	System	29 Jul 2020 14:21:33

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:21:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f5876e0f-fe03-4e4d-a5ae-a646f3c379bb'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:21:33
User entered 'None (1)'	System	29 Jul 2020 14:21:33

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:21:30', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f5876e0f-fe03-4e4d-a5ae-a646f3c379bb'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:21:33
User entered '29 Jul 2020 10:21'	System	29 Jul 2020 14:21:33

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '29 Jul 2020 10:01'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 10:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
User entered '29 Jul 2020 12:31'	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 12:31'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 13:50:38
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:17:19', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '343d87c1-2371-4c8f-9148-b87ff28d4dfa'	(b) (4), (b) (6) System	30 Jul 2020 00:17:43
User entered 'None (1)'	System	30 Jul 2020 00:17:43

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:17:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '343d87c1-2371-4c8f-9148-b87ff28d4dfa'	(b) (4), (b) (6) System	30 Jul 2020 00:17:43
User entered 'No (N)'	System	30 Jul 2020 00:17:43

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:17:28', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '343d87c1-2371-4c8f-9148-b87ff28d4dfa'	(b) (4), (b) (6) System	30 Jul 2020 00:17:43
User entered 'No (N)'	System	30 Jul 2020 00:17:43

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:17:33', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '343d87c1-2371-4c8f-9148-b87ff28d4dfa'	(b) (4), (b) (6) System	30 Jul 2020 00:17:43
User entered 'None (1)'	System	30 Jul 2020 00:17:43

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:17:39', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '343d87c1-2371-4c8f-9148-b87ff28d4dfa'	(b) (4), (b) (6) System	30 Jul 2020 00:17:43
User entered '29 Jul 2020 20:17'	System	30 Jul 2020 00:17:43

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '29 Jul 2020 13:26'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 13:26'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '30 Jul 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '29 Jul 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 2'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:19:27', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e128f397-c1bb-4a15-9efc-d9359add3554'	(b) (4), (b) (6)	31 Jul 2020 00:20:12
User entered 'None (1)'	System	31 Jul 2020 00:20:12

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:19:30', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e128f397-c1bb-4a15-9efc-d9359add3554'	(b) (4), (b) (6) System	31 Jul 2020 00:20:12
User entered 'No (N)'	System	31 Jul 2020 00:20:12

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:19:52', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e128f397-c1bb-4a15-9efc-d9359add3554'	(b) (4), (b) (6) System	31 Jul 2020 00:20:12
User entered 'No (N)'	System	31 Jul 2020 00:20:12

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:19:59', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e128f397-c1bb-4a15-9efc-d9359add3554'	(b) (4), (b) (6)	31 Jul 2020 00:20:12
User entered 'None (1)'	System	31 Jul 2020 00:20:12

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:20:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e128f397-c1bb-4a15-9efc-d9359add3554'	(b) (4), (b) (6)	
	System	31 Jul 2020 00:20:12
User entered '30 Jul 2020 20:20'	System	31 Jul 2020 00:20:12

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '30 Jul 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '29 Jul 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '31 Jul 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 3'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:13:03', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '3a4ea666-f819-4fae-a5f3-b87709394bfa'	(b) (4), (b) (6) System	01 Aug 2020 10:13:32
User entered 'None (1)'	System	01 Aug 2020 10:13:32

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:13:07', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '3a4ea666-f819-4fae-a5f3-b87709394bfa'	(b) (4), (b) (6) System	01 Aug 2020 10:13:32
User entered 'No (N)'	System	01 Aug 2020 10:13:32

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:13:11', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '3a4ea666-f819-4fae-a5f3-b87709394bfa'	(b) (4), (b) (6)	
	System	01 Aug 2020 10:13:32
User entered 'No (N)'	System	01 Aug 2020 10:13:32

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:13:17', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '3a4ea666-f819-4fae-a5f3-b87709394bfa'	(b) (4), (b) (6) System	01 Aug 2020 10:13:32
User entered 'None (1)'	System	01 Aug 2020 10:13:32

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:13:27', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '3a4ea666-f819-4fae-a5f3-b87709394bfa'	(b) (4), (b) (6) System	01 Aug 2020 10:13:32
User entered '01 Aug 2020 06:13'	System	01 Aug 2020 10:13:32

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '31 Jul 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '01 Aug 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 4'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '923c8c99-175d-4549-81f2-a83a5d831de0'	(b) (4), (b) (6) System	02 Aug 2020 06:46:35
User entered 'None (1)'	System	02 Aug 2020 06:46:35

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:15', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '923c8c99-175d-4549-81f2-a83a5d831de0'	(b) (4), (b) (6)	
	System	02 Aug 2020 06:46:35
User entered 'No (N)'	System	02 Aug 2020 06:46:35

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:18', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '923c8c99-175d-4549-81f2-a83a5d831de0'	(b) (4), (b) (6) System	02 Aug 2020 06:46:35
User entered 'No (N)'	System	02 Aug 2020 06:46:35

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:24', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '923c8c99-175d-4549-81f2-a83a5d831de0'	(b) (4), (b) (6) System	02 Aug 2020 06:46:35
User entered 'None (1)'	System	02 Aug 2020 06:46:35

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:31', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '923c8c99-175d-4549-81f2-a83a5d831de0'	(b) (4), (b) (6) System	02 Aug 2020 06:46:35
User entered '02 Aug 2020 02:46'	System	02 Aug 2020 06:46:35

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '01 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Aug 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 5'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:31', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '734c9213-1ca9-4e47-8fe6-60c8cd87fbc2'	(b) (4), (b) (6) System	03 Aug 2020 01:22:45
User entered 'None (1)'	System	03 Aug 2020 01:22:45

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:35', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '734c9213-1ca9-4e47-8fe6-60c8cd87fbc2'	(b) (4), (b) (6) System	03 Aug 2020 01:22:45
User entered 'No (N)'	System	03 Aug 2020 01:22:45

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:37', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '734c9213-1ca9-4e47-8fe6-60c8cd87fbc2'	(b) (4), (b) (6) System	03 Aug 2020 01:22:45
User entered 'No (N)'	System	03 Aug 2020 01:22:45

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:40', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '734c9213-1ca9-4e47-8fe6-60c8cd87fbc2'	(b) (4), (b) (6) System	03 Aug 2020 01:22:45
User entered 'None (1)'	System	03 Aug 2020 01:22:45

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:43', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '734c9213-1ca9-4e47-8fe6-60c8cd87fbc2'	(b) (4), (b) (6)	
	System	03 Aug 2020 01:22:45
User entered '02 Aug 2020 21:22'	System	03 Aug 2020 01:22:45

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Aug 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 6'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:39', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1fb92724-780e-41b7-9efd-9be42375b6f9'	(b) (4), (b) (6) System	04 Aug 2020 09:15:08
User entered 'None (1)'	System	04 Aug 2020 09:15:08

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:42', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1fb92724-780e-41b7-9efd-9be42375b6f9'	(b) (4), (b) (6)	
	System	04 Aug 2020 09:15:08
User entered 'No (N)'	System	04 Aug 2020 09:15:08

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:44', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1fb92724-780e-41b7-9efd-9be42375b6f9'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Aug 2020 09:15:08

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:47', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1fb92724-780e-41b7-9efd-9be42375b6f9'	(b) (4), (b) (6)	04 Aug 2020 09:15:08
User entered 'None (1)'	System	04 Aug 2020 09:15:08

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:50', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1fb92724-780e-41b7-9efd-9be42375b6f9'	(b) (4), (b) (6)	
	System	04 Aug 2020 09:15:08
User entered '04 Aug 2020 05:14'	System	04 Aug 2020 09:15:08

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Aug 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 7'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:48:45', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '42db325a-7c93-42e3-9990-0e5d3fa07f49'	(b) (4), (b) (6) System	05 Aug 2020 07:49:09
User entered 'None (1)'	System	05 Aug 2020 07:49:09

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:48:47', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '42db325a-7c93-42e3-9990-0e5d3fa07f49'	(b) (4), (b) (6)	
	System	05 Aug 2020 07:49:09
User entered 'No (N)'	System	05 Aug 2020 07:49:09

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:48:49', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '42db325a-7c93-42e3-9990-0e5d3fa07f49'	(b) (4), (b) (6)	
	System	05 Aug 2020 07:49:09
User entered 'No (N)'	System	05 Aug 2020 07:49:09

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:48:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '42db325a-7c93-42e3-9990-0e5d3fa07f49'	(b) (4), (b) (6) System	05 Aug 2020 07:49:09
User entered 'None (1)'	System	05 Aug 2020 07:49:09

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:49:03', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '42db325a-7c93-42e3-9990-0e5d3fa07f49'	(b) (4), (b) (6)	
	System	05 Aug 2020 07:49:09
User entered '05 Aug 2020 03:49'	System	05 Aug 2020 07:49:09

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 14:04:52
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 13:50:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:21:39', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '50cee64c-870e-4ef3-aec2-206116b5a03b'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:22:29
User entered 'None (0)'	System	29 Jul 2020 14:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:21:46', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '50cee64c-870e-4ef3-aec2-206116b5a03b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	29 Jul 2020 14:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:21:50', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '50cee64c-870e-4ef3-aec2-206116b5a03b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	29 Jul 2020 14:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:21:57', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '50cee64c-870e-4ef3-aec2-206116b5a03b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	29 Jul 2020 14:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:22:01', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '50cee64c-870e-4ef3-aec2-206116b5a03b'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:22:29
User entered 'None (0)'	System	29 Jul 2020 14:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:22:04', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '50cee64c-870e-4ef3-aec2-206116b5a03b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	29 Jul 2020 14:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:22:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '50cee64c-870e-4ef3-aec2-206116b5a03b'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:22:29
User entered 'No (N)'	System	29 Jul 2020 14:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T10:22:26', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '50cee64c-870e-4ef3-aec2-206116b5a03b'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:22:29
User entered '29 Jul 2020 10:22'	System	29 Jul 2020 14:22:29

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '29 Jul 2020 10:01'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 10:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '29 Jul 2020 12:31'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 12:31'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:17:52', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6abe411d-1666-4fc3-af44-262e0d643aa8'	(b) (4), (b) (6)	
	System	30 Jul 2020 00:18:37
User entered 'No interference with activity (1)'	System	30 Jul 2020 00:18:37

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:17:57', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6abe411d-1666-4fc3-af44-262e0d643aa8'	(b) (4), (b) (6) System	30 Jul 2020 00:18:37
User entered 'None (0)'	System	30 Jul 2020 00:18:37

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:18:02', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6abe411d-1666-4fc3-af44-262e0d643aa8'	(b) (4), (b) (6)	
User entered 'None (0)'	System	30 Jul 2020 00:18:37

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:18:08', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6abe411d-1666-4fc3-af44-262e0d643aa8'	(b) (4), (b) (6)	
User entered 'None (0)'	System	30 Jul 2020 00:18:37

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:18:12', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6abe411d-1666-4fc3-af44-262e0d643aa8'	(b) (4), (b) (6)	
User entered 'None (0)'	System	30 Jul 2020 00:18:37

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:18:17', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6abe411d-1666-4fc3-af44-262e0d643aa8'	(b) (4), (b) (6)	
	System	30 Jul 2020 00:18:37
User entered 'None (0)'	System	30 Jul 2020 00:18:37

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:18:22', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6abe411d-1666-4fc3-af44-262e0d643aa8'	(b) (4), (b) (6) System	30 Jul 2020 00:18:37
User entered 'No (N)'	System	30 Jul 2020 00:18:37

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-29T20:18:30', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6abe411d-1666-4fc3-af44-262e0d643aa8'	(b) (4), (b) (6)	
	System	30 Jul 2020 00:18:37
User entered '29 Jul 2020 20:18'	System	30 Jul 2020 00:18:37

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '29 Jul 2020 13:26'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '28 Jul 2020 13:26'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 14:04:52
User entered '29 Jul 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 2'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:20:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0cc76516-b855-48a9-8845-94fb66d046ce'	(b) (4), (b) (6)	
	System	31 Jul 2020 00:21:00
User entered 'No interference with activity (1)'	System	31 Jul 2020 00:21:00

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:20:27', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0cc76516-b855-48a9-8845-94fb66d046ce'	(b) (4), (b) (6)	
	System	31 Jul 2020 00:21:00
User entered 'None (0)'	System	31 Jul 2020 00:21:00

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:20:30', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0cc76516-b855-48a9-8845-94fb66d046ce'	(b) (4), (b) (6)	
User entered 'None (0)'	System	31 Jul 2020 00:21:00

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:20:35', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0cc76516-b855-48a9-8845-94fb66d046ce'	(b) (4), (b) (6)	
User entered 'None (0)'	System	31 Jul 2020 00:21:00

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:20:41', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0cc76516-b855-48a9-8845-94fb66d046ce'	(b) (4), (b) (6)	
User entered 'None (0)'	System	31 Jul 2020 00:21:00

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:20:45', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0cc76516-b855-48a9-8845-94fb66d046ce'	(b) (4), (b) (6)	
	System	31 Jul 2020 00:21:00
User entered 'None (0)'	System	31 Jul 2020 00:21:00

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:20:48', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0cc76516-b855-48a9-8845-94fb66d046ce'	(b) (4), (b) (6)	
	System	31 Jul 2020 00:21:00
User entered 'No (N)'	System	31 Jul 2020 00:21:00

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-07-30T20:20:57', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0cc76516-b855-48a9-8845-94fb66d046ce'	(b) (4), (b) (6) System	31 Jul 2020 00:21:00
User entered '30 Jul 2020 20:20'	System	31 Jul 2020 00:21:00

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '30 Jul 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '29 Jul 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '31 Jul 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 3'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:13:52', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1cea7d3d-c96a-4e3c-a29d-8f5d3844cf50'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Aug 2020 10:14:19

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:13:56', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1cea7d3d-c96a-4e3c-a29d-8f5d3844cf50'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Aug 2020 10:14:19

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:13:59', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1cea7d3d-c96a-4e3c-a29d-8f5d3844cf50'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Aug 2020 10:14:19

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:14:01', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1cea7d3d-c96a-4e3c-a29d-8f5d3844cf50'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Aug 2020 10:14:19

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:14:03', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1cea7d3d-c96a-4e3c-a29d-8f5d3844cf50'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Aug 2020 10:14:19

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:14:05', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1cea7d3d-c96a-4e3c-a29d-8f5d3844cf50'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Aug 2020 10:14:19

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:14:12', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1cea7d3d-c96a-4e3c-a29d-8f5d3844cf50'	(b) (4), (b) (6)	
User entered 'No (N)'	System	01 Aug 2020 10:14:19

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-01T06:14:17', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1cea7d3d-c96a-4e3c-a29d-8f5d3844cf50'	(b) (4), (b) (6)	
	System	01 Aug 2020 10:14:19
User entered '01 Aug 2020 06:14'	System	01 Aug 2020 10:14:19

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '31 Jul 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '01 Aug 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 4'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:36', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'bd7434e3-4ece-4f84-9a07-25e8be33ac0f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Aug 2020 06:47:18

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:42', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'bd7434e3-4ece-4f84-9a07-25e8be33ac0f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Aug 2020 06:47:18

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:46', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'bd7434e3-4ece-4f84-9a07-25e8be33ac0f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Aug 2020 06:47:18

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:51', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'bd7434e3-4ece-4f84-9a07-25e8be33ac0f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Aug 2020 06:47:18

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'bd7434e3-4ece-4f84-9a07-25e8be33ac0f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Aug 2020 06:47:18

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:46:56', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'bd7434e3-4ece-4f84-9a07-25e8be33ac0f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Aug 2020 06:47:18

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:47:04', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'bd7434e3-4ece-4f84-9a07-25e8be33ac0f'	(b) (4), (b) (6)	
User entered 'No (N)'	System	02 Aug 2020 06:47:18

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T02:47:14', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'bd7434e3-4ece-4f84-9a07-25e8be33ac0f'	(b) (4), (b) (6)	
User entered '02 Aug 2020 02:47'	System	02 Aug 2020 06:47:18

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '01 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Aug 2020 11:59'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 5'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:48', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '8230c4cd-bc16-4a73-a54e-b4bf1550ade8'	(b) (4), (b) (6) System	03 Aug 2020 01:23:11
User entered 'None (0)'	System	03 Aug 2020 01:23:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:50', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '8230c4cd-bc16-4a73-a54e-b4bf1550ade8'	(b) (4), (b) (6) System	03 Aug 2020 01:23:11
User entered 'None (0)'	System	03 Aug 2020 01:23:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:52', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '8230c4cd-bc16-4a73-a54e-b4bf1550ade8'	(b) (4), (b) (6)	
User entered 'None (0)'	System	03 Aug 2020 01:23:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '8230c4cd-bc16-4a73-a54e-b4bf1550ade8'	(b) (4), (b) (6) System	03 Aug 2020 01:23:11
User entered 'None (0)'	System	03 Aug 2020 01:23:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:56', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '8230c4cd-bc16-4a73-a54e-b4bf1550ade8'	(b) (4), (b) (6)	
User entered 'None (0)'	System	03 Aug 2020 01:23:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:22:58', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '8230c4cd-bc16-4a73-a54e-b4bf1550ade8'	(b) (4), (b) (6) System	03 Aug 2020 01:23:11
User entered 'None (0)'	System	03 Aug 2020 01:23:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:23:03', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '8230c4cd-bc16-4a73-a54e-b4bf1550ade8'	(b) (4), (b) (6) System	03 Aug 2020 01:23:11
User entered 'No (N)'	System	03 Aug 2020 01:23:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-02T21:23:06', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '8230c4cd-bc16-4a73-a54e-b4bf1550ade8'	(b) (4), (b) (6)	03 Aug 2020 01:23:11
User entered '02 Aug 2020 21:23'	System	03 Aug 2020 01:23:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 14:04:52
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 6'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '03992f91-2281-40c3-b03d-d54ec45a415d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Aug 2020 09:15:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:56', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '03992f91-2281-40c3-b03d-d54ec45a415d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Aug 2020 09:15:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:14:59', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '03992f91-2281-40c3-b03d-d54ec45a415d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Aug 2020 09:15:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:15:01', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '03992f91-2281-40c3-b03d-d54ec45a415d'	(b) (4), (b) (6)	04 Aug 2020 09:15:11
User entered 'None (0)'	System	04 Aug 2020 09:15:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:15:02', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '03992f91-2281-40c3-b03d-d54ec45a415d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Aug 2020 09:15:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:15:04', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '03992f91-2281-40c3-b03d-d54ec45a415d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Aug 2020 09:15:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:15:06', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '03992f91-2281-40c3-b03d-d54ec45a415d'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Aug 2020 09:15:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-04T05:15:08', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '03992f91-2281-40c3-b03d-d54ec45a415d'	(b) (4), (b) (6)	
	System	04 Aug 2020 09:15:11
User entered '04 Aug 2020 05:15'	System	04 Aug 2020 09:15:11

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 14:04:52
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 7'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:49:07', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '251556aa-0eb0-4028-9048-3f344afbcc60'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Aug 2020 07:49:26

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:49:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '251556aa-0eb0-4028-9048-3f344afbcc60'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Aug 2020 07:49:26

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:49:10', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '251556aa-0eb0-4028-9048-3f344afbcc60'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Aug 2020 07:49:26

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:49:12', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '251556aa-0eb0-4028-9048-3f344afbcc60'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Aug 2020 07:49:26

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:49:14', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '251556aa-0eb0-4028-9048-3f344afbcc60'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Aug 2020 07:49:26

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:49:16', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '251556aa-0eb0-4028-9048-3f344afbcc60'	(b) (4), (b) (6)	
	System	05 Aug 2020 07:49:26
User entered 'None (0)'	System	05 Aug 2020 07:49:26

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:49:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '251556aa-0eb0-4028-9048-3f344afbcc60'	(b) (4), (b) (6) System	05 Aug 2020 07:49:26
User entered 'No (N)'	System	05 Aug 2020 07:49:26

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b93a7b1c283cb920)', Time: '2020-08-05T03:49:24', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '251556aa-0eb0-4028-9048-3f344afbcc60'	(b) (4), (b) (6)	
	System	05 Aug 2020 07:49:26
User entered '05 Aug 2020 03:49'	System	05 Aug 2020 07:49:26

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Aug 2020 12:00'	(b) (4), (b) (6)	
	System	29 Jul 2020 14:04:52
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 13:50:38

US3022065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 14:04:52
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:20:19
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 19:49:22

US3022065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:20:19
User entered '06 Aug 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 19:49:22

US3022065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:20:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 19:49:22

US3022065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:20:19
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 19:49:22

US3022065

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:20:30
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 19:49:27

US3022065

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered 'I'	(b) (4), (b) (6) System	06 Aug 2020 19:49:27

US3022065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:02
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	17 Aug 2020 23:24:56

US3022065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:02
User entered '14 Aug 2020'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	17 Aug 2020 23:24:56

US3022065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	17 Aug 2020 23:24:56

US3022065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:02
User entered empty.	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	17 Aug 2020 23:24:56

US3022065

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:09
User entered 'Yes (Y)'	(b) (4), (b) (6) Morgan Deal (b) (4) (b) (4)	17 Aug 2020 23:25:01

US3022065

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:55:45
User entered '1'	(b) (4), (b) (6) System	17 Aug 2020 23:25:01

US3022065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:00
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:16
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 13:06:46

US3022065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:00
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:16
User entered '20 Aug 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 13:06:46

US3022065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:00
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 13:06:46

US3022065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:00
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:16
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 13:06:46

US3022065

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:00
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:22
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 13:06:50

US3022065

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:00
User entered 'I'	(b) (4), (b) (6) System	01 Sep 2020 13:06:50

US3022065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:24:58
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	02 Sep 2020 20:50:06
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:24:58
	(b) (4), (b) (6)	
User entered '2 Sep 2020'	Stella Yoon (b) (4)	02 Sep 2020 20:50:06
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[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 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:24:58
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4)	02 Sep 2020 20:50:06
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'VISIT2'	(b) (4), (b) (6) System	02 Sep 2020 20:50:06

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Yoon (b) (4)	02 Sep 2020 20:51:37
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered 'Yes (Y)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:06
	(b) (4), (b) (6)	
User entered '2 Sep 2020'	Stella Yoon (b) (4)	02 Sep 2020 20:51:37
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:06
	(b) (4), (b) (6)	
User entered '15:58'	Stella Yoon (b) (4)	02 Sep 2020 20:51:37
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered '2 Sep 2020 15:58'	(b) (4), (b) (6) System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:06
	(b) (4), (b) (6)	
User entered '36.7' C	Stella Yoon (b) (4)	02 Sep 2020 20:51:37
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered 'Oral (Oral)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:06
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4)	02 Sep 2020 20:51:37
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered '74'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'bpm'	(b) (4), (b) (6) System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered '12'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'breaths/min'	(b) (4), (b) (6) System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered '138'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'mmHg'	(b) (4), (b) (6) System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered '75'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'mmHg'	(b) (4), (b) (6) System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered 'Yes (Y)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:06
	(b) (4), (b) (6)	
User entered '2 Sep 2020'	Stella Yoon (b) (4)	02 Sep 2020 20:51:37
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:06
	(b) (4), (b) (6)	
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	02 Sep 2020 20:51:48
User entered '16:35' reason for change: Data Entry Error	Stella Yoon (b) (4)	02 Sep 2020 20:51:48
	(b) (4)	
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	02 Sep 2020 20:51:37
User entered '13:35'	Stella Yoon (b) (4)	02 Sep 2020 20:51:37
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User entered '2 Sep 2020 16:35'	System	02 Sep 2020 20:51:48
User entered '2 Sep 2020 13:35'	System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:06
	(b) (4), (b) (6)	
User entered '36.8' C	Stella Yoon (b) (4)	02 Sep 2020 20:51:37
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered 'Oral (Oral)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:06
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4)	02 Sep 2020 20:51:37
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered '85'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'bpm'	(b) (4), (b) (6) System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered '14'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'breaths/min'	(b) (4), (b) (6) System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered '138'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'mmHg'	(b) (4), (b) (6) System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:06
User entered '88'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'mmHg'	(b) (4), (b) (6) System	02 Sep 2020 20:51:37

US3022065

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:13
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	02 Sep 2020 20:52:03
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:13
	(b) (4), (b) (6)	
User entered '2 Sep 2020'	Stella Yoon (b) (4)	02 Sep 2020 20:52:03
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:28
User entered 'Yes (Y)'	(b) (4), (b) (6) Chevon Roberts (b) (4) (b) (4)	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:28
User entered empty.	(b) (4), (b) (6) Chevon Roberts (b) (4) (b) (4)	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

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 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:28
User entered empty.	(b) (4), (b) (6) Chevon Roberts (b) (4) (b) (4)	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:28
User entered '02 Sep 2020'	(b) (4), (b) (6) Chevon Roberts (b) (4) (b) (4)	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:28
User entered '16:04'	(b) (4), (b) (6) Chevon Roberts (b) (4) (b) (4)	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered '02 Sep 2020 16:04'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:28
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6) Chevon Roberts (b) (4) (b) (4)	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Sep 2020 19:25:28
User entered 'ONCE'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:36
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	02 Sep 2020 20:52:59
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:36
	(b) (4), (b) (6)	
User entered '2 Sep 2020'	Stella Yoon (b) (4)	02 Sep 2020 20:52:59
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:36
	(b) (4), (b) (6)	
User entered '08:44'	Stella Yoon (b) (4)	02 Sep 2020 20:52:59
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered '2 Sep 2020 08:44'	(b) (4), (b) (6) System	02 Sep 2020 20:52:59

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:52:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:42
	(b) (4), (b) (6)	
User entered '2 Sep 2020'	Stella Yoon (b) (4)	02 Sep 2020 20:53:15
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:53:15

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:42
User entered 'Yes (Y)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:53:15

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:42
	(b) (4), (b) (6)	
User entered '09:12'	Stella Yoon (b) (4)	02 Sep 2020 20:53:15
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered '2 Sep 2020 09:12'	(b) (4), (b) (6) System	02 Sep 2020 20:53:15

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:53:15

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:25:42
User entered 'No (N)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	02 Sep 2020 20:53:15

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:42
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4)	02 Sep 2020 20:53:15
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered empty.	(b) (4), (b) (6) System	02 Sep 2020 20:53:15

US3022065

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:25:49
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	02 Sep 2020 20:53:20
	(b) (4)	

US3022065

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered '1'	(b) (4), (b) (6) System	02 Sep 2020 20:53:20

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:31:21', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0caf8927-4ce1-4a2b-96d0-cf3aa1d66c42'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	02 Sep 2020 20:31:50

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:31:27', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0caf8927-4ce1-4a2b-96d0-cf3aa1d66c42'	(b) (4), (b) (6)	
User entered '98.3'	System	02 Sep 2020 20:31:50

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:31:37', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0caf8927-4ce1-4a2b-96d0-cf3aa1d66c42'	(b) (4), (b) (6)	
User entered 'No (N)'	System	02 Sep 2020 20:31:50

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:31:46', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0caf8927-4ce1-4a2b-96d0-cf3aa1d66c42'	(b) (4), (b) (6)	
	System	02 Sep 2020 20:31:50
User entered '02 Sep 2020 16:31'	System	02 Sep 2020 20:31:50

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Sep 2020 16:24'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Sep 2020 18:54'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:03', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'fcaab355-48bc-4bfd-ad08-2375da7fef93'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	03 Sep 2020 00:56:26

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:12', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'fcaab355-48bc-4bfd-ad08-2375da7fef93'	(b) (4), (b) (6)	
User entered '98.6'	System	03 Sep 2020 00:56:26

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:15', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'fcaab355-48bc-4bfd-ad08-2375da7fef93'	(b) (4), (b) (6) System	03 Sep 2020 00:56:26
User entered 'No (N)'	System	03 Sep 2020 00:56:26

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:21', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'fcaab355-48bc-4bfd-ad08-2375da7fef93'	(b) (4), (b) (6) System	03 Sep 2020 00:56:26
User entered '02 Sep 2020 20:56'	System	03 Sep 2020 00:56:26

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Sep 2020 19:49'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 2'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:07:37', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '74cee1d6-c999-45d8-921e-9d017beb0dde'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	04 Sep 2020 00:08:02

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:07:44', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '74cee1d6-c999-45d8-921e-9d017beb0dde'	(b) (4), (b) (6)	
User entered '96.5'	System	04 Sep 2020 00:08:02

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:07:50', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '74cee1d6-c999-45d8-921e-9d017beb0dde'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Sep 2020 00:08:02

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:07:56', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '74cee1d6-c999-45d8-921e-9d017beb0dde'	(b) (4), (b) (6) System	04 Sep 2020 00:08:02
User entered '03 Sep 2020 20:07'	System	04 Sep 2020 00:08:02

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 3'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f40a8ff0-c27d-4198-ad67-b7b03c56a2cf'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	05 Sep 2020 10:21:28

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:15', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f40a8ff0-c27d-4198-ad67-b7b03c56a2cf'	(b) (4), (b) (6)	
User entered '97.6'	System	05 Sep 2020 10:21:28

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:18', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f40a8ff0-c27d-4198-ad67-b7b03c56a2cf'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Sep 2020 10:21:28

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f40a8ff0-c27d-4198-ad67-b7b03c56a2cf'	(b) (4), (b) (6) System	05 Sep 2020 10:21:28
User entered '05 Sep 2020 06:21'	System	05 Sep 2020 10:21:28

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 4'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:31:47', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'cb315ed6-96c4-4812-8b14-690669253def'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	06 Sep 2020 01:32:01

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:31:52', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'cb315ed6-96c4-4812-8b14-690669253def'	(b) (4), (b) (6)	
User entered '97.4'	System	06 Sep 2020 01:32:01

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:31:55', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'cb315ed6-96c4-4812-8b14-690669253def'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Sep 2020 01:32:01

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:31:58', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'cb315ed6-96c4-4812-8b14-690669253def'	(b) (4), (b) (6)	
User entered '05 Sep 2020 21:31'	System	06 Sep 2020 01:32:01

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 5'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:36:36', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '231d40ed-dd31-47d0-9909-498c0c86ed3c'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	07 Sep 2020 09:37:02

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:36:42', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '231d40ed-dd31-47d0-9909-498c0c86ed3c'	(b) (4), (b) (6)	
User entered '97.5'	System	07 Sep 2020 09:37:02

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:36:47', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '231d40ed-dd31-47d0-9909-498c0c86ed3c'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Sep 2020 09:37:02

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:36:55', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '231d40ed-dd31-47d0-9909-498c0c86ed3c'	(b) (4), (b) (6)	
User entered '07 Sep 2020 05:36'	System	07 Sep 2020 09:37:02

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 6'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:13', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6c68b2d3-4d92-4eeb-82bc-10cfale166ff'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	07 Sep 2020 21:17:33

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:19', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6c68b2d3-4d92-4eeb-82bc-10cfale166ff'	(b) (4), (b) (6)	
User entered '97.8'	System	07 Sep 2020 21:17:33

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6c68b2d3-4d92-4eeb-82bc-10cfale166ff'	(b) (4), (b) (6) System	07 Sep 2020 21:17:33
User entered 'No (N)'	System	07 Sep 2020 21:17:33

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:25', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6c68b2d3-4d92-4eeb-82bc-10cfale166ff'	(b) (4), (b) (6) System	07 Sep 2020 21:17:33
User entered '07 Sep 2020 17:17'	System	07 Sep 2020 21:17:33

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 7'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6967e1ab-9bef-4531-8305-703d846c2c42'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	09 Sep 2020 00:21:43

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:28', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6967e1ab-9bef-4531-8305-703d846c2c42'	(b) (4), (b) (6)	09 Sep 2020 00:21:43
User entered '97.4'	System	09 Sep 2020 00:21:43

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:34', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6967e1ab-9bef-4531-8305-703d846c2c42'	(b) (4), (b) (6) System	09 Sep 2020 00:21:43
User entered 'No (N)'	System	09 Sep 2020 00:21:43

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:38', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '6967e1ab-9bef-4531-8305-703d846c2c42'	(b) (4), (b) (6) System	09 Sep 2020 00:21:43
User entered '08 Sep 2020 20:21'	System	09 Sep 2020 00:21:43

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:31:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '14631788-42ce-403a-8d95-edc31eef98bb'	(b) (4), (b) (6)	
	System	02 Sep 2020 20:32:53
User entered 'None (1)'	System	02 Sep 2020 20:32:53

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:31:59', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '14631788-42ce-403a-8d95-ed31eef98bb'	(b) (4), (b) (6)	
User entered 'No (N)'	System	02 Sep 2020 20:32:53

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:32:18', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '14631788-42ce-403a-8d95-ed31eef98bb'	(b) (4), (b) (6)	
	System	02 Sep 2020 20:32:53
User entered 'No (N)'	System	02 Sep 2020 20:32:53

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:32:44', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '14631788-42ce-403a-8d95-edc31eef98bb'	(b) (4), (b) (6)	02 Sep 2020 20:32:53
User entered 'None (1)'	System	02 Sep 2020 20:32:53

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:32:48', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '14631788-42ce-403a-8d95-ed31eef98bb'	(b) (4), (b) (6)	
	System	02 Sep 2020 20:32:53
User entered '02 Sep 2020 16:32'	System	02 Sep 2020 20:32:53

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Sep 2020 16:24'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Sep 2020 18:54'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:29', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '55f87dda-26f1-4415-8bcf-f05dbd9b2924'	(b) (4), (b) (6)	
	System	03 Sep 2020 00:56:55
User entered 'None (1)'	System	03 Sep 2020 00:56:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:42', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '55f87dda-26f1-4415-8bcf-f05dbd9b2924'	(b) (4), (b) (6) System	03 Sep 2020 00:56:55
User entered 'No (N)'	System	03 Sep 2020 00:56:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:46', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '55f87dda-26f1-4415-8bcf-f05dbd9b2924'	(b) (4), (b) (6)	
User entered 'No (N)'	System	03 Sep 2020 00:56:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:49', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '55f87dda-26f1-4415-8bcf-f05dbd9b2924'	(b) (4), (b) (6)	
User entered 'None (1)'	System	03 Sep 2020 00:56:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '55f87dda-26f1-4415-8bcf-f05dbd9b2924'	(b) (4), (b) (6)	
User entered '02 Sep 2020 20:56'	System	03 Sep 2020 00:56:55
	System	03 Sep 2020 00:56:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Sep 2020 19:49'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 2'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:08:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd72a14d5-596e-4d53-991a-79a4a61fbe1f'	(b) (4), (b) (6)	
User entered 'None (1)'	System	04 Sep 2020 00:08:36

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:08:14', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd72a14d5-596e-4d53-991a-79a4a61fbe1f'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Sep 2020 00:08:36

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:08:17', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd72a14d5-596e-4d53-991a-79a4a61fbe1f'	System	04 Sep 2020 00:08:36
User entered 'No (N)'	System	04 Sep 2020 00:08:36

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:08:27', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd72a14d5-596e-4d53-991a-79a4a61fbe1f'	(b) (4), (b) (6)	
User entered 'None (1)'	System	04 Sep 2020 00:08:36

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:08:32', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd72a14d5-596e-4d53-991a-79a4a61fbe1f'	(b) (4), (b) (6)	
User entered '03 Sep 2020 20:08'	System	04 Sep 2020 00:08:36

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 3'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:26', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '22d02260-0907-446c-a6df-da4aea29433a'	(b) (4), (b) (6) System	05 Sep 2020 10:21:55
User entered 'None (1)'	System	05 Sep 2020 10:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:30', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '22d02260-0907-446c-a6df-da4aea29433a'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Sep 2020 10:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:33', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '22d02260-0907-446c-a6df-da4aea29433a'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Sep 2020 10:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:36', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '22d02260-0907-446c-a6df-da4aea29433a'	(b) (4), (b) (6)	05 Sep 2020 10:21:55
User entered 'None (1)'	System	05 Sep 2020 10:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:39', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '22d02260-0907-446c-a6df-da4aea29433a'	(b) (4), (b) (6)	
	System	05 Sep 2020 10:21:55
User entered '05 Sep 2020 06:21'	System	05 Sep 2020 10:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 4'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:03', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '311378c5-4d0e-4eaf-a490-10ec701b8d91'	(b) (4), (b) (6)	
	System	06 Sep 2020 01:32:15
User entered 'None (1)'	System	06 Sep 2020 01:32:15

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:05', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '311378c5-4d0e-4eaf-a490-10ec701b8d91'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Sep 2020 01:32:15

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:07', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '311378c5-4d0e-4eaf-a490-10ec701b8d91'	(b) (4), (b) (6)	
	System	06 Sep 2020 01:32:15
User entered 'No (N)'	System	06 Sep 2020 01:32:15

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '311378c5-4d0e-4eaf-a490-10ec701b8d91'	(b) (4), (b) (6)	
	System	06 Sep 2020 01:32:15
User entered 'None (1)'	System	06 Sep 2020 01:32:15

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:12', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '311378c5-4d0e-4eaf-a490-10ec701b8d91'	(b) (4), (b) (6)	
	System	06 Sep 2020 01:32:15
User entered '05 Sep 2020 21:32'	System	06 Sep 2020 01:32:15

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 5'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:36:58', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '9af1915e-6e17-4cde-969b-36864a172a1b'	(b) (4), (b) (6)	07 Sep 2020 09:37:18
User entered 'None (1)'	System	07 Sep 2020 09:37:18

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:01', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '9af1915e-6e17-4cde-969b-36864a172a1b'	(b) (4), (b) (6)	
	System	07 Sep 2020 09:37:18
User entered 'No (N)'	System	07 Sep 2020 09:37:18

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:03', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '9af1915e-6e17-4cde-969b-36864a172a1b'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Sep 2020 09:37:18

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:05', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '9af1915e-6e17-4cde-969b-36864a172a1b'	(b) (4), (b) (6)	
	System	07 Sep 2020 09:37:18
User entered 'None (1)'	System	07 Sep 2020 09:37:18

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:14', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '9af1915e-6e17-4cde-969b-36864a172a1b'	(b) (4), (b) (6)	
	System	07 Sep 2020 09:37:18
User entered '07 Sep 2020 05:37'	System	07 Sep 2020 09:37:18

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 6'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:28', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1e53753c-ec69-4d7d-8a6c-d79bfe904503'	(b) (4), (b) (6)	07 Sep 2020 21:17:44
User entered 'None (1)'	System	07 Sep 2020 21:17:44

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:31', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1e53753c-ec69-4d7d-8a6c-d79bfe904503'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Sep 2020 21:17:44

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:33', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1e53753c-ec69-4d7d-8a6c-d79bfe904503'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Sep 2020 21:17:44

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:34', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1e53753c-ec69-4d7d-8a6c-d79bfe904503'	(b) (4), (b) (6)	
	System	07 Sep 2020 21:17:44
User entered 'None (1)'	System	07 Sep 2020 21:17:44

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:38', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1e53753c-ec69-4d7d-8a6c-d79bfe904503'	(b) (4), (b) (6)	
	System	07 Sep 2020 21:17:44
User entered '07 Sep 2020 17:17'	System	07 Sep 2020 21:17:44

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 7'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:42', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f612541d-6a8e-4504-9e16-1337c4195237'	(b) (4), (b) (6) System	09 Sep 2020 00:21:55
User entered 'None (1)'	System	09 Sep 2020 00:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:44', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f612541d-6a8e-4504-9e16-1337c4195237'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Sep 2020 00:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:46', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f612541d-6a8e-4504-9e16-1337c4195237'	(b) (4), (b) (6) System	09 Sep 2020 00:21:55
User entered 'No (N)'	System	09 Sep 2020 00:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:48', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f612541d-6a8e-4504-9e16-1337c4195237'	(b) (4), (b) (6)	09 Sep 2020 00:21:55
User entered 'None (1)'	System	09 Sep 2020 00:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:51', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f612541d-6a8e-4504-9e16-1337c4195237'	(b) (4), (b) (6) System	09 Sep 2020 00:21:55
User entered '08 Sep 2020 20:21'	System	09 Sep 2020 00:21:55

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:32:57', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1622973c-5b84-4dc5-bba8-311bdc993db6'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Sep 2020 20:33:23

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:33:00', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1622973c-5b84-4dc5-bba8-311bdc993db6'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Sep 2020 20:33:23

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:33:04', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1622973c-5b84-4dc5-bba8-311bdc993db6'	(b) (4), (b) (6) System	02 Sep 2020 20:33:23
User entered 'None (0)'	System	02 Sep 2020 20:33:23

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:33:06', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1622973c-5b84-4dc5-bba8-311bdc993db6'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Sep 2020 20:33:23

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:33:11', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1622973c-5b84-4dc5-bba8-311bdc993db6'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Sep 2020 20:33:23

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:33:13', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1622973c-5b84-4dc5-bba8-311bdc993db6'	(b) (4), (b) (6)	
User entered 'None (0)'	System	02 Sep 2020 20:33:23

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:33:16', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1622973c-5b84-4dc5-bba8-311bdc993db6'	(b) (4), (b) (6) System	02 Sep 2020 20:33:23
User entered 'No (N)'	System	02 Sep 2020 20:33:23

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T16:33:19', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1622973c-5b84-4dc5-bba8-311bdc993db6'	(b) (4), (b) (6)	
	System	02 Sep 2020 20:33:23
User entered '02 Sep 2020 16:33'	System	02 Sep 2020 20:33:23

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Sep 2020 16:24'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Sep 2020 18:54'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:56:59', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd7a4758b-c70b-4dba-b13f-76c4a15d34a0'	(b) (4), (b) (6)	
User entered 'None (0)'	System	03 Sep 2020 00:57:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:57:02', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd7a4758b-c70b-4dba-b13f-76c4a15d34a0'	(b) (4), (b) (6)	
User entered 'None (0)'	System	03 Sep 2020 00:57:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:57:05', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd7a4758b-c70b-4dba-b13f-76c4a15d34a0'	(b) (4), (b) (6)	
User entered 'None (0)'	System	03 Sep 2020 00:57:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:57:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd7a4758b-c70b-4dba-b13f-76c4a15d34a0'	(b) (4), (b) (6)	
User entered 'None (0)'	System	03 Sep 2020 00:57:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:57:25', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd7a4758b-c70b-4dba-b13f-76c4a15d34a0'	(b) (4), (b) (6)	
User entered 'None (0)'	System	03 Sep 2020 00:57:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:57:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd7a4758b-c70b-4dba-b13f-76c4a15d34a0'	(b) (4), (b) (6)	
User entered 'None (0)'	System	03 Sep 2020 00:57:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:57:29', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd7a4758b-c70b-4dba-b13f-76c4a15d34a0'	(b) (4), (b) (6)	
User entered 'No (N)'	System	03 Sep 2020 00:57:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-02T20:57:33', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd7a4758b-c70b-4dba-b13f-76c4a15d34a0'	(b) (4), (b) (6)	
	System	03 Sep 2020 00:57:36
User entered '02 Sep 2020 20:57'	System	03 Sep 2020 00:57:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '02 Sep 2020 19:49'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 2'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:08:43', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '4258c8bb-d70a-4c1d-bc91-91f142f483ec'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:09:15

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:08:47', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '4258c8bb-d70a-4c1d-bc91-91f142f483ec'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:09:15

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:08:51', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '4258c8bb-d70a-4c1d-bc91-91f142f483ec'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:09:15

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:08:58', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '4258c8bb-d70a-4c1d-bc91-91f142f483ec'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:09:15

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:09:01', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '4258c8bb-d70a-4c1d-bc91-91f142f483ec'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:09:15

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:09:05', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '4258c8bb-d70a-4c1d-bc91-91f142f483ec'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:09:15

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:09:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '4258c8bb-d70a-4c1d-bc91-91f142f483ec'	(b) (4), (b) (6)	
	System	04 Sep 2020 00:09:15
User entered 'No (N)'	System	04 Sep 2020 00:09:15

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-03T20:09:12', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '4258c8bb-d70a-4c1d-bc91-91f142f483ec'	(b) (4), (b) (6) System	04 Sep 2020 00:09:15
User entered '03 Sep 2020 20:09'	System	04 Sep 2020 00:09:15

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 3'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:43', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '768ef63e-fe26-41cf-9b8b-4dac68c7d119'	(b) (4), (b) (6)	
	System	05 Sep 2020 10:22:10
User entered 'None (0)'	System	05 Sep 2020 10:22:10

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:48', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '768ef63e-fe26-41cf-9b8b-4dac68c7d119'	(b) (4), (b) (6) System	05 Sep 2020 10:22:10
User entered 'None (0)'	System	05 Sep 2020 10:22:10

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:55', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '768ef63e-fe26-41cf-9b8b-4dac68c7d119'	(b) (4), (b) (6)	
	System	05 Sep 2020 10:22:10
User entered 'None (0)'	System	05 Sep 2020 10:22:10

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:21:58', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '768ef63e-fe26-41cf-9b8b-4dac68c7d119'	(b) (4), (b) (6) System	05 Sep 2020 10:22:10
User entered 'None (0)'	System	05 Sep 2020 10:22:10

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:22:00', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '768ef63e-fe26-41cf-9b8b-4dac68c7d119'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 10:22:10

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:22:02', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '768ef63e-fe26-41cf-9b8b-4dac68c7d119'	(b) (4), (b) (6) System	05 Sep 2020 10:22:10
User entered 'None (0)'	System	05 Sep 2020 10:22:10

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:22:05', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '768ef63e-fe26-41cf-9b8b-4dac68c7d119'	(b) (4), (b) (6) System	05 Sep 2020 10:22:10
User entered 'No (N)'	System	05 Sep 2020 10:22:10

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T06:22:07', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '768ef63e-fe26-41cf-9b8b-4dac68c7d119'	(b) (4), (b) (6) System	05 Sep 2020 10:22:10
User entered '05 Sep 2020 06:22'	System	05 Sep 2020 10:22:10

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 4'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:15', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b08be22a-247d-4c70-b429-e863e9a2bcc3'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Sep 2020 01:32:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:17', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b08be22a-247d-4c70-b429-e863e9a2bcc3'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Sep 2020 01:32:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:18', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b08be22a-247d-4c70-b429-e863e9a2bcc3'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Sep 2020 01:32:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b08be22a-247d-4c70-b429-e863e9a2bcc3'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Sep 2020 01:32:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:21', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b08be22a-247d-4c70-b429-e863e9a2bcc3'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Sep 2020 01:32:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b08be22a-247d-4c70-b429-e863e9a2bcc3'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Sep 2020 01:32:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:26', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b08be22a-247d-4c70-b429-e863e9a2bcc3'	(b) (4), (b) (6) System	06 Sep 2020 01:32:36
User entered 'No (N)'	System	06 Sep 2020 01:32:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-05T21:32:28', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b08be22a-247d-4c70-b429-e863e9a2bcc3'	(b) (4), (b) (6)	
	System	06 Sep 2020 01:32:36
User entered '05 Sep 2020 21:32'	System	06 Sep 2020 01:32:36

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 5'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:17', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de9f2428-3c50-4737-8ec5-6cbdba8357ee'	System	07 Sep 2020 09:37:37
User entered 'None (0)'	System	07 Sep 2020 09:37:37

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:18', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de9f2428-3c50-4737-8ec5-6cbdba8357ee'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 09:37:37

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de9f2428-3c50-4737-8ec5-6cbdba8357ee'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 09:37:37

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:21', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de9f2428-3c50-4737-8ec5-6cbdba8357ee'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 09:37:37

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de9f2428-3c50-4737-8ec5-6cbdba8357ee'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 09:37:37

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:25', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de9f2428-3c50-4737-8ec5-6cbdba8357ee'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 09:37:37

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:27', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de9f2428-3c50-4737-8ec5-6cbdba8357ee'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Sep 2020 09:37:37

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T05:37:31', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de9f2428-3c50-4737-8ec5-6cbdba8357ee'	(b) (4), (b) (6) System	07 Sep 2020 09:37:37
User entered '07 Sep 2020 05:37'	System	07 Sep 2020 09:37:37

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 6'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:46', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '15c67c28-3e96-4b2b-83f2-1b2a8981d43d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 21:18:11

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:49', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '15c67c28-3e96-4b2b-83f2-1b2a8981d43d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 21:18:11

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '15c67c28-3e96-4b2b-83f2-1b2a8981d43d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 21:18:11

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:57', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '15c67c28-3e96-4b2b-83f2-1b2a8981d43d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 21:18:11

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:17:58', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '15c67c28-3e96-4b2b-83f2-1b2a8981d43d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 21:18:11

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:18:00', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '15c67c28-3e96-4b2b-83f2-1b2a8981d43d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 21:18:11

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:18:04', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '15c67c28-3e96-4b2b-83f2-1b2a8981d43d'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Sep 2020 21:18:11

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-07T17:18:07', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '15c67c28-3e96-4b2b-83f2-1b2a8981d43d'	(b) (4), (b) (6)	
	System	07 Sep 2020 21:18:11
User entered '07 Sep 2020 17:18'	System	07 Sep 2020 21:18:11

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	02 Sep 2020 20:11:58
User entered 'Day 7'	System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:56', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b3a9fe91-6c0a-431f-a800-543e8ecaf49d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	09 Sep 2020 00:22:13

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:57', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b3a9fe91-6c0a-431f-a800-543e8ecaf49d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	09 Sep 2020 00:22:13

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:21:59', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b3a9fe91-6c0a-431f-a800-543e8ecaf49d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	09 Sep 2020 00:22:13

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:22:00', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b3a9fe91-6c0a-431f-a800-543e8ecaf49d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	09 Sep 2020 00:22:13

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:22:02', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b3a9fe91-6c0a-431f-a800-543e8ecaf49d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	09 Sep 2020 00:22:13

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:22:03', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b3a9fe91-6c0a-431f-a800-543e8ecaf49d'	(b) (4), (b) (6)	
User entered 'None (0)'	System	09 Sep 2020 00:22:13

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:22:06', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b3a9fe91-6c0a-431f-a800-543e8ecaf49d'	(b) (4), (b) (6)	
	System	09 Sep 2020 00:22:13
User entered 'No (N)'	System	09 Sep 2020 00:22:13

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-09-08T20:22:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'b3a9fe91-6c0a-431f-a800-543e8ecaf49d'	(b) (4), (b) (6) System	09 Sep 2020 00:22:13
User entered '08 Sep 2020 20:22'	System	09 Sep 2020 00:22:13

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	02 Sep 2020 20:11:58

US3022065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:28
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 15:17:34

US3022065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:28
User entered '11 Sep 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 15:17:34

US3022065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 15:17:34

US3022065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:28
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 15:17:34

US3022065

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:33
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 15:17:38

US3022065

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'I'	(b) (4), (b) (6) System	16 Sep 2020 15:17:38

US3022065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:46
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 15:17:52

US3022065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:21:46
	(b) (4), (b) (6)	
User entered '16 Sep 2020'	Shanice Bennett (b) (4)	16 Sep 2020 15:17:52
	(b) (4)	

US3022065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 15:17:52

US3022065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:21:46
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 15:17:52

US3022065

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:21:55
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Sep 2020 15:17:55
	(b) (4)	

US3022065

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'I'	(b) (4), (b) (6) System	16 Sep 2020 15:17:55

US3022065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:22:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:53:01
	(b) (4), (b) (6)	

US3022065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:22:02
	(b) (4), (b) (6)	
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 15:53:01
	(b) (4), (b) (6)	

US3022065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:22:02
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 15:53:01
	(b) (4), (b) (6)	

US3022065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:22:02
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 15:53:01

US3022065

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:22:09
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:53:08
	(b) (4), (b) (6)	

US3022065

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'I'	(b) (4), (b) (6) System	23 Sep 2020 15:53:08

US3022065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:06
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:18:34
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:06
	(b) (4), (b) (6)	
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:18:34
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[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 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:06
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Sep 2020 15:18:34
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'VISIT3'	(b) (4), (b) (6) System	30 Sep 2020 15:18:34

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered '11:00'	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered '30 Sep 2020 11:00'	(b) (4), (b) (6) System	30 Sep 2020 15:19:21

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered '37.1' C	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered '72'	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'bpm'	(b) (4), (b) (6) System	30 Sep 2020 15:19:21

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered '14'	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'breaths/min'	(b) (4), (b) (6) System	30 Sep 2020 15:19:21

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered '120'	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'mmHg'	(b) (4), (b) (6) System	30 Sep 2020 15:19:21

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:12
	(b) (4), (b) (6)	
User entered '78'	(b) (4), (b) (6)	30 Sep 2020 15:19:21
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'mmHg'	(b) (4), (b) (6) System	30 Sep 2020 15:19:21

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:19:42
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:19
	(b) (4), (b) (6)	
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:19:42
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:25
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:19:56
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:25
	(b) (4), (b) (6)	
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:19:56
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:25
	(b) (4), (b) (6)	
User entered '11:06'	(b) (4), (b) (6)	30 Sep 2020 15:19:56
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered '30 Sep 2020 11:06'	(b) (4), (b) (6) System	30 Sep 2020 15:19:56

US3022065

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:26:30
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:20:00
	(b) (4), (b) (6)	

US3022065

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered '1'	(b) (4), (b) (6) System	30 Sep 2020 15:20:00

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 64'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-10-01T14:24:43', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '9743b9ca-7d84-480f-816b-6b6226088ac3'	(b) (4), (b) (6)	01 Oct 2020 18:24:58
User entered 'No (N)'	System	01 Oct 2020 18:24:58

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-10-01T14:24:46', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '9743b9ca-7d84-480f-816b-6b6226088ac3'	(b) (4), (b) (6) System	01 Oct 2020 18:24:58
User entered 'No (N)'	System	01 Oct 2020 18:24:58

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-10-01T14:24:50', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '9743b9ca-7d84-480f-816b-6b6226088ac3'	(b) (4), (b) (6) System	01 Oct 2020 18:24:58
User entered '01 Oct 2020 14:24:50'	System	01 Oct 2020 18:24:58

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '27 Sep 2020 00:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '01 Oct 2020 23:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 13:50:38
User entered 'Day 71'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '04 Oct 2020 00:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '08 Oct 2020 23:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 13:50:38
User entered 'Day 78'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '11 Oct 2020 00:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '15 Oct 2020 23:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 92'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-10-27T17:41:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '08e565d1-8322-434b-b3bb-48b1b04ea569'	(b) (4), (b) (6) System	27 Oct 2020 21:42:10
User entered 'Yes (Y)'	System	27 Oct 2020 21:42:10

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-10-27T17:41:29', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '08e565d1-8322-434b-b3bb-48b1b04ea569'	(b) (4), (b) (6)	27 Oct 2020 21:42:10
User entered 'No (N)'	System	27 Oct 2020 21:42:10

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-10-27T17:41:36', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '08e565d1-8322-434b-b3bb-48b1b04ea569'	(b) (4), (b) (6) System	27 Oct 2020 21:42:10
User entered 'No (N)'	System	27 Oct 2020 21:42:10

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-10-27T17:41:41', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '08e565d1-8322-434b-b3bb-48b1b04ea569'	(b) (4), (b) (6)	27 Oct 2020 21:42:10
User entered 'Yes (Y)'	System	27 Oct 2020 21:42:10

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Please 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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-10-27T17:41:50', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '08e565d1-8322-434b-b3bb-48b1b04ea569'	(b) (4), (b) (6)	27 Oct 2020 21:42:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Oct 2020 21:42:10

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-10-27T17:41:55', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '08e565d1-8322-434b-b3bb-48b1b04ea569' User entered '27 Oct 2020 17:41:55'	(b) (4), (b) (6) System	27 Oct 2020 21:42:10
	System	27 Oct 2020 21:42:10

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '25 Oct 2020 00:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '29 Oct 2020 23:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
Data entry locked.	(b) (4), (b) (6)	
	System	29 Jul 2020 13:50:38
User entered 'Day 99'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-11-05T18:15:13', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1835d431-aae2-45d1-8634-095e6fd08fc9'	(b) (4), (b) (6)	05 Nov 2020 23:15:33
User entered 'Yes (Y)'	System	05 Nov 2020 23:15:33

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-11-05T18:15:17', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1835d431-aae2-45d1-8634-095e6fd08fc9'	(b) (4), (b) (6)	05 Nov 2020 23:15:33
User entered 'No (N)'	System	05 Nov 2020 23:15:33

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-11-05T18:15:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1835d431-aae2-45d1-8634-095e6fd08fc9'	(b) (4), (b) (6)	05 Nov 2020 23:15:33
User entered 'No (N)'	System	05 Nov 2020 23:15:33

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-11-05T18:15:24', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1835d431-aae2-45d1-8634-095e6fd08fc9'	(b) (4), (b) (6)	05 Nov 2020 23:15:33
User entered 'No (N)'	System	05 Nov 2020 23:15:33

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-11-05T18:15:28', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '1835d431-aae2-45d1-8634-095e6fd08fc9'	(b) (4), (b) (6)	
User entered '05 Nov 2020 18:15:28'	System	05 Nov 2020 23:15:33

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '01 Nov 2020 00:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:08
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '05 Nov 2020 23:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 13:50:38
User entered 'Day 106'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 14:52:39

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '08 Nov 2020 00:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '12 Nov 2020 23:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 13:50:38
User entered 'Day 113'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 14:52:39

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '15 Nov 2020 00:01'	System	29 Jul 2020 13:50:38

US3022065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:50
Data entry locked.	System	29 Jul 2020 14:04:52
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 14:04:52
Data entry unlocked.	System	29 Jul 2020 14:04:52
Data entry locked.	System	29 Jul 2020 13:50:38
User entered '19 Nov 2020 23:59'	System	29 Jul 2020 13:50:38

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (0be8106eecf1476a)', Time: '2020-12-15T16:27:45', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '5b402087-c9d1-4572-bf41-04483a19d42c'	System	15 Dec 2020 21:28:09
User entered 'No (N)'	System	15 Dec 2020 21:28:09

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you been exposed to someone with 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 (0be8106eecf1476a)', Time: '2020-12-15T16:27:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '5b402087-c9d1-4572-bf41-04483a19d42c'	System	15 Dec 2020 21:28:09
User entered 'No (N)'	System	15 Dec 2020 21:28:09

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-12-15T16:27:57', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '5b402087-c9d1-4572-bf41-04483a19d42c'	System	15 Dec 2020 21:28:09
User entered '15 Dec 2020 16:27:57'	System	15 Dec 2020 21:28:09

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (0be8106eecf1476a)', Time: '2020-12-20T13:08:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f0aad547-7684-4f9e-a6f4-8c9e69a19cfe'	System	20 Dec 2020 18:08:29
User entered 'No (N)'	System	20 Dec 2020 18:08:29

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you been exposed to someone with 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 (0be8106eecf1476a)', Time: '2020-12-20T13:08:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f0aad547-7684-4f9e-a6f4-8c9e69a19cfe'	System	20 Dec 2020 18:08:29
User entered 'No (N)'	System	20 Dec 2020 18:08:29

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-12-20T13:08:27', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f0aad547-7684-4f9e-a6f4-8c9e69a19cfe'	System	20 Dec 2020 18:08:29
User entered '20 Dec 2020 13:08:27'	System	20 Dec 2020 18:08:29

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (0be8106eecf1476a)', Time: '2020-12-25T04:47:28', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f7f3cb05-0ebe-46e2-bd2a-62a489e2d3a3'	System	25 Dec 2020 09:47:40
User entered 'No (N)'	System	25 Dec 2020 09:47:40

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you been exposed to someone with 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 (0be8106eecf1476a)', Time: '2020-12-25T04:47:32', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f7f3cb05-0ebe-46e2-bd2a-62a489e2d3a3'	System	25 Dec 2020 09:47:40
User entered 'No (N)'	System	25 Dec 2020 09:47:40

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0be8106eecf1476a)', Time: '2020-12-25T04:47:36', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'f7f3cb05-0ebe-46e2-bd2a-62a489e2d3a3' User entered '25 Dec 2020 04:47:36'	System	25 Dec 2020 09:47:40
	System	25 Dec 2020 09:47:40

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-01-19T08:30:59', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0f1ce73f-ca95-42d1-917f-a912a8b1658e'	System	19 Jan 2021 13:31:14
User entered 'No (N)'	System	19 Jan 2021 13:31:14

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-01-19T08:31:06', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0f1ce73f-ca95-42d1-917f-a912a8b1658e'	System	19 Jan 2021 13:31:14
User entered 'No (N)'	System	19 Jan 2021 13:31:14

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-01-19T08:31:10', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '0f1ce73f-ca95-42d1-917f-a912a8b1658e' User entered '19 Jan 2021 08:31:10'	System	19 Jan 2021 13:31:14

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-01-25T17:42:26', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '3bbbadf4-489f-4d1f-81b9-d25e14e9d88b'	System	25 Jan 2021 22:46:01
User entered 'No (N)'	System	25 Jan 2021 22:46:01

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-01-25T17:42:33', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '3bbbadf4-489f-4d1f-81b9-d25e14e9d88b'	System	25 Jan 2021 22:46:01
User entered 'Yes (Y)'	System	25 Jan 2021 22:46:01

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Please 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 (967bf95a7eb4818c)', Time: '2021-01-25T17:42:41', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '3bbbadf4-489f-4d1f-81b9-d25e14e9d88b'	System	25 Jan 2021 22:46:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 22:46:01

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-01-25T17:45:50', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '3bbbadf4-489f-4d1f-81b9-d25e14e9d88b' User entered '25 Jan 2021 17:45:50'	System	25 Jan 2021 22:46:01

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-01-31T19:42:42', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '216009f8-d906-40f5-b841-83dba9a1019a'	System	01 Feb 2021 00:42:59
User entered 'No (N)'	System	01 Feb 2021 00:42:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-01-31T19:42:53', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '216009f8-d906-40f5-b841-83dba9a1019a'	System	01 Feb 2021 00:42:59
User entered 'No (N)'	System	01 Feb 2021 00:42:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-01-31T19:42:57', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '216009f8-d906-40f5-b841-83dba9a1019a'	System	01 Feb 2021 00:42:59
User entered '31 Jan 2021 19:42:57'	System	01 Feb 2021 00:42:59

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-02-07T08:44:44', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'c226668c-d37a-46e9-a49b-3130f190d329'	System	07 Feb 2021 13:45:13
User entered 'No (N)'	System	07 Feb 2021 13:45:13

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-02-07T08:44:49', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'c226668c-d37a-46e9-a49b-3130f190d329'	System	07 Feb 2021 13:45:13
User entered 'No (N)'	System	07 Feb 2021 13:45:13

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-02-07T08:45:09', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'c226668c-d37a-46e9-a49b-3130f190d329'	System	07 Feb 2021 13:45:13
User entered '07 Feb 2021 08:45:09'	System	07 Feb 2021 13:45:13

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-02-16T16:22:22', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'dc9a36c7-a542-4bdd-b28d-629c344e3857'	System	16 Feb 2021 21:23:33
User entered 'No (N)'	System	16 Feb 2021 21:23:33

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-02-16T16:22:31', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'dc9a36c7-a542-4bdd-b28d-629c344e3857'	System	16 Feb 2021 21:23:33
User entered 'No (N)'	System	16 Feb 2021 21:23:33

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-02-16T16:22:34', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'dc9a36c7-a542-4bdd-b28d-629c344e3857'	System	16 Feb 2021 21:23:33
User entered '16 Feb 2021 16:22:34'	System	16 Feb 2021 21:23:33

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-02-22T05:40:41', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de14179b-2187-4b9f-945a-cac25712a32f'	System	22 Feb 2021 10:40:52
User entered 'No (N)'	System	22 Feb 2021 10:40:52

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-02-22T05:40:45', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de14179b-2187-4b9f-945a-cac25712a32f'	System	22 Feb 2021 10:40:52
User entered 'No (N)'	System	22 Feb 2021 10:40:52

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-02-22T05:40:48', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'de14179b-2187-4b9f-945a-cac25712a32f' User entered '22 Feb 2021 05:40:48'	System	22 Feb 2021 10:40:52

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-02-28T09:52:34', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '70b3f5d4-7fca-4a86-9eb4-a8f896469543'	System	28 Feb 2021 14:52:46
User entered 'No (N)'	System	28 Feb 2021 14:52:46

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-02-28T09:52:38', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '70b3f5d4-7fca-4a86-9eb4-a8f896469543'	System	28 Feb 2021 14:52:46
User entered 'No (N)'	System	28 Feb 2021 14:52:46

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-02-28T09:52:41', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '70b3f5d4-7fca-4a86-9eb4-a8f896469543' User entered '28 Feb 2021 09:52:41'	System	28 Feb 2021 14:52:46
	System	28 Feb 2021 14:52:46

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-03-08T18:13:59', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '98d5a320-d014-40d1-959a-2a10e9a13b57'	System	08 Mar 2021 23:19:16
User entered 'No (N)'	System	08 Mar 2021 23:19:16

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-03-08T18:14:08', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '98d5a320-d014-40d1-959a-2a10e9a13b57'	System	08 Mar 2021 23:19:16
User entered 'No (N)'	System	08 Mar 2021 23:19:16

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-03-08T18:14:12', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '98d5a320-d014-40d1-959a-2a10e9a13b57'	System	08 Mar 2021 23:19:16
User entered '08 Mar 2021 18:14:12'	System	08 Mar 2021 23:19:16

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-03-15T08:01:15', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9b28194-cb47-4313-a460-1df4322cc7cd'	System	15 Mar 2021 12:01:27
User entered 'No (N)'	System	15 Mar 2021 12:01:27

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-03-15T08:01:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9b28194-cb47-4313-a460-1df4322cc7cd'	System	15 Mar 2021 12:01:27
User entered 'No (N)'	System	15 Mar 2021 12:01:27

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-03-15T08:01:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9b28194-cb47-4313-a460-1df4322cc7cd' User entered '15 Mar 2021 08:01:23'	System	15 Mar 2021 12:01:27
	System	15 Mar 2021 12:01:27

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-03-23T16:30:12', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9fb8ae7-de5a-48a1-a190-d565e9489bd7'	System	23 Mar 2021 20:30:33
User entered 'No (N)'	System	23 Mar 2021 20:30:33

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-03-23T16:30:20', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9fb8ae7-de5a-48a1-a190-d565e9489bd7'	System	23 Mar 2021 20:30:33
User entered 'No (N)'	System	23 Mar 2021 20:30:33

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-03-23T16:30:27', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e9fb8ae7-de5a-48a1-a190-d565e9489bd7' User entered '23 Mar 2021 16:30:27'	System	23 Mar 2021 20:30:33

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-03-29T11:50:16', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e98763f0-8a67-4331-a006-1320838e5d8a'	System	29 Mar 2021 15:50:30
User entered 'No (N)'	System	29 Mar 2021 15:50:30

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-03-29T11:50:22', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e98763f0-8a67-4331-a006-1320838e5d8a'	System	29 Mar 2021 15:50:30
User entered 'No (N)'	System	29 Mar 2021 15:50:30

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-03-29T11:50:25', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'e98763f0-8a67-4331-a006-1320838e5d8a'	System	29 Mar 2021 15:50:30
User entered '29 Mar 2021 11:50:25'	System	29 Mar 2021 15:50:30

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-04-06T19:01:22', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '7d844c57-37f2-4826-99a0-85640f9680c3'	System	06 Apr 2021 23:04:23
User entered 'No (N)'	System	06 Apr 2021 23:04:23

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-04-06T19:01:25', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '7d844c57-37f2-4826-99a0-85640f9680c3'	System	06 Apr 2021 23:04:23
User entered 'No (N)'	System	06 Apr 2021 23:04:23

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-04-06T19:01:30', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: '7d844c57-37f2-4826-99a0-85640f9680c3'	System	06 Apr 2021 23:04:23
User entered '06 Apr 2021 19:01:30'	System	06 Apr 2021 23:04:23

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-04-18T07:24:23', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'fd652224-324e-4f6a-a388-7657d9920c5f'	System	18 Apr 2021 11:24:39
User entered 'No (N)'	System	18 Apr 2021 11:24:39

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-04-18T07:24:26', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'fd652224-324e-4f6a-a388-7657d9920c5f'	System	18 Apr 2021 11:24:39
User entered 'No (N)'	System	18 Apr 2021 11:24:39

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-04-18T07:24:34', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'fd652224-324e-4f6a-a388-7657d9920c5f' User entered '18 Apr 2021 07:24:34'	System	18 Apr 2021 11:24:39
	System	18 Apr 2021 11:24:39

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-04-26T12:42:18', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'a21e2fd2-c4b4-4028-8fe7-e2e63627cfec'	System	26 Apr 2021 16:42:39
User entered 'No (N)'	System	26 Apr 2021 16:42:39

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-04-26T12:42:26', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'a21e2fd2-c4b4-4028-8fe7-e2e63627cfec'	System	26 Apr 2021 16:42:39
User entered 'No (N)'	System	26 Apr 2021 16:42:39

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-04-26T12:42:30', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'a21e2fd2-c4b4-4028-8fe7-e2e63627cfec'	System	26 Apr 2021 16:42:39
User entered '26 Apr 2021 12:42:30'	System	26 Apr 2021 16:42:39

US3022065

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[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 (967bf95a7eb4818c)', Time: '2021-05-03T12:57:45-04:00', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'c5c6f4d1-4359-433c-b6b3-89f46a18d311'	System	03 May 2021 16:58:10
User entered 'No (N)'	System	03 May 2021 16:58:10

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

Have you been exposed to someone with 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 (967bf95a7eb4818c)', Time: '2021-05-03T12:57:51-04:00', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'c5c6f4d1-4359-433c-b6b3-89f46a18d311'	System	03 May 2021 16:58:10
User entered 'No (N)'	System	03 May 2021 16:58:10

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-05-03T12:57:59-04:00', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'c5c6f4d1-4359-433c-b6b3-89f46a18d311'	System	03 May 2021 16:58:10
User entered '03 May 2021 12:57:59'	System	03 May 2021 16:58:10

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:39:50

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:39:50

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:39:50

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:39:50

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:39:50

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:39:50

US3022065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:50
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:39:50

US3022065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:52:39

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 08:38:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-02-28T09:52:48', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd2c70642-4e1e-4edc-afe6-d8b50979ae65'	(b) (4), (b) (6)	28 Feb 2021 14:52:57
User entered 'No (N)'	System	28 Feb 2021 14:52:57

US3022065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:52:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (967bf95a7eb4818c)', Time: '2021-02-28T09:52:54', User OID: 'PatientReportedOutcome (US3022065)', ODM File OID: 'd2c70642-4e1e-4edc-afe6-d8b50979ae65'	(b) (4), (b) (6)	28 Feb 2021 14:52:57
User entered '28 Feb 2021 09:52:54'	System	28 Feb 2021 14:52:57

US3022065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 19:48:36
	(b) (4), (b) (6)	
User closed query 'Per source call was not attempted please verify.' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 19:40:57
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
Query 'Per source call was not attempted please verify.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:56:23
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4), (b) (6) System	10 Mar 2021 20:56:15
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	10 Mar 2021 20:55:58
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 20:55:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 20:55:58
User opened query 'Per source call was not attempted please verify.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 20:02:19
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:25
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	28 Jan 2021 13:39:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 13:39:35
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	28 Jan 2021 13:38:50

US3022065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 13:38:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 14:10:27

US3022065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 19:48:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:56:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 20:56:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(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)	29 Jan 2021 08:27:03
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 is correct' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 13:39:17
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 13:39:08
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	28 Jan 2021 13:38:50
User entered '02 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 13:38:50
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) (b) (4), (b) (6)	04 Dec 2020 12:31:21

US3022065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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 IS CORRECT' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 14:10:39
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	03 Dec 2020 14:10:27
User entered '30 Nov 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 14:10:27

US3022065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 19:48:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:56:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 20:56:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:38:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 14:10:27

US3022065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 19:48:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:56:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 20:56:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Subject was in convalescent period' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:38:50
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 14:10:27

US3022065

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 19:48:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 14:10:51

US3022065

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:32
User entered 'I'	(b) (4), (b) (6) System	03 Dec 2020 14:10:51

US3022065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 19:42:17

US3022065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '30 Nov 2020'	(b) (4), (b) (6)	29 Dec 2020 19:42:17

US3022065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Dec 2020 19:42:17

US3022065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:42:17

US3022065

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 19:42:23

US3022065

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
User entered 'I'	System	29 Dec 2020 19:42:23

US3022065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:37:33
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 19:42:35

US3022065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:37:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '29 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 19:42:35

US3022065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:37:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Dec 2020 19:42:35

US3022065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:37:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:42:35

US3022065

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:40:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 19:42:41

US3022065

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
User entered 'I'	System	29 Dec 2020 19:42:41

US3022065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:43:33
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 19:11:11

US3022065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:43:33
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '01 Feb 2021'	(b) (4), (b) (6)	01 Feb 2021 19:11:11

US3022065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:43:33
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 19:11:11

US3022065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:43:33
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 19:11:11

US3022065

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:43:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 19:11:24

US3022065

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:25:10
User entered 'I'	System	01 Feb 2021 19:11:24

US3022065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed .Vital signs if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:21:12
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed .Vital signs if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:22:51
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed .Vital signs if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:28:31
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:28:31
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'No required per protocol.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:17:04

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Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:30:12
	(b) (4), (b) (6)	09 Mar 2021 18:44:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:31:17
	(b) (4), (b) (6)	

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Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:44:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
User entered '16 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 17:31:17
	(b) (4), (b) (6)	

US3022065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[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 09:28:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:44:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Feb 2021 17:31:17
	(b) (4), (b) (6)	

US3022065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
User entered 'VISIT4'	(b) (4), (b) (6) System	19 Feb 2021 17:31:17

US3022065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:46:49
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered 'No (N)'	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:46:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
User entered '16 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:47:00
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
User entered '16:14' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User entered '16 Feb 2021 16:14'	System	08 Apr 2021 18:22:41
User entered empty.	System	30 Mar 2021 16:21:16

US3022065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:47:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
User entered '36.7' C reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:47:24
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:47:30
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User entered 'bpm'	System	08 Apr 2021 18:22:41
User entered empty.	System	30 Mar 2021 16:21:16

US3022065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:47:35
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	08 Apr 2021 18:22:41
User entered empty.	System	30 Mar 2021 16:21:16

US3022065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:47:38
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
User entered '135' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User entered 'mmHg'	System	08 Apr 2021 18:22:41
User entered empty.	System	30 Mar 2021 16:21:16

US3022065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:47:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:22:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:14
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:21:16
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
User entered 'mmHg'	System	08 Apr 2021 18:22:41
User entered empty.	System	30 Mar 2021 16:21:16

US3022065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:28:36

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:28:36

US3022065

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:44:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:31:38
	(b) (4), (b) (6)	

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:44:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
User entered '16 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 17:31:38
	(b) (4), (b) (6)	

US3022065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:45:07
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:56:00
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	03 Mar 2021 16:00:23
	(b) (4)	

US3022065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:45:07
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:56:00
	(b) (4)	
User entered '16 Feb 2021'	Chevon Roberts (b) (4)	03 Mar 2021 16:00:23
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:45:07
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:56:00
	(b) (4)	
User entered '16:51'	Chevon Roberts (b) (4)	03 Mar 2021 16:00:23
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
User entered '16 Feb 2021 16:51'	(b) (4), (b) (6) System	03 Mar 2021 16:00:23

US3022065

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:47:24
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:31:44
	(b) (4), (b) (6)	

US3022065

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:28:36
User entered '1'	(b) (4), (b) (6) System	19 Feb 2021 17:31:44

US3022065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 19:37:39

US3022065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	29 Mar 2021 19:37:51
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	29 Mar 2021 19:37:51
User entered '29 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 19:37:51
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Mar 2021 19:37:39
User entered '23 Mar 2021'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 19:37:39

US3022065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 19:37:39

US3022065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 19:37:39

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 19:37:45

US3022065

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:37:45

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:52:39

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:45:02
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 12:50:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 12:50:45
User entered '26 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 12:50:45
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 12:50:18
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 12:50:18
User entered '26 Oct 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:50:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:52:39

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:45:05
	(b) (4), (b) (6)	
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 18:45:04
	(b) (4), (b) (6)	
Query 'Please provide source.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 12:50:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	13 Nov 2020 12:50:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 12:50:45
User entered '11:00' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 12:50:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	13 Nov 2020 12:50:18
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 12:50:18
User opened query 'Please provide source.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:17:54
User entered '09:19'	(b) (4), (b) (6)	27 Oct 2020 12:50:21
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:52:39

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:21
User entered '26 Oct 2020 11:00'	(b) (4), (b) (6)	
	System	13 Nov 2020 12:50:45
User entered empty.	System	13 Nov 2020 12:50:18
User entered '26 Oct 2020 09:19'	System	27 Oct 2020 12:50:21

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:52:39

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:45:18
	(b) (4), (b) (6)	
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 21:08:19
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 12:50:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 12:50:45
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 12:50:45
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 12:50:18
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 12:50:18
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:50:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

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[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:45:20
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 12:50:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 12:50:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 12:50:45
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 12:50:18
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 12:50:18
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:50:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:43:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:27:22
	(b) (4), (b) (6)	
User entered '24 Oct 2020' reason for change: Data	(b) (4), (b) (6)	08 Dec 2020 13:27:22
Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered '26 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:51:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User closed query 'Per CDM (re-query): Response is noted, however please remove the % units of O2 Saturation of this and below field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:36:10
Query 'Per CDM (re-query): Response is noted, however please remove the % units of O2 Saturation of this and below field. Thank you. ' answered with 'it will not let me remove %' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:47:19
User opened query 'Per CDM (re-query): Response is noted, however please remove the % units of O2 Saturation of this and below field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 07:40:37
User closed query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1 and 2. If not collected, please consider recording these as NOT DONE.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 07:40:37
Query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1 and 2. If not collected, please consider recording these as NOT DONE.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 20:00:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 20:00:38
User opened query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1 and 2. If not collected, please consider recording these as NOT DONE.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 19:54:38
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:27:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 13:27:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:51:46

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
User entered '%'	(b) (4), (b) (6)	
User entered empty.	System	06 Jan 2021 20:00:38
User entered '%'	System	08 Dec 2020 13:27:22
User entered '%'	System	27 Oct 2020 12:51:46

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:51:24
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	06 Jan 2021 20:00:38
change Data Entry Error	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:27:22
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry	(b) (4), (b) (6)	08 Dec 2020 13:27:22
Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
	(b) (4), (b) (6)	
User entered '36.8' C	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Severe (Severe)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Severe (Severe)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Severe (Severe)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:51:46

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Severe (Severe)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Severe (Severe)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:51:46

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:51:46

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:52:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Oct 2020 12:51:46
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
	(b) (4), (b) (6)	
User entered '25 Oct 2020' reason for change: Data	(b) (4), (b) (6)	08 Dec 2020 13:28:17
Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 13:28:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered '99'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
User entered empty.	(b) (4), (b) (6)	
User entered '%'	System	08 Dec 2020 13:28:17
	System	28 Oct 2020 17:40:29

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 13:28:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered '97.0' F	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 13:28:17
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	08 Dec 2020 13:28:17
Data Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:23
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
	(b) (4), (b) (6)	
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	08 Dec 2020 13:28:17
Data Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	08 Dec 2020 13:28:17
Data Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
	(b) (4), (b) (6)	
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	08 Dec 2020 13:28:17
Data Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:29
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
	(b) (4), (b) (6)	
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	08 Dec 2020 13:28:17
Data Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
	(b) (4), (b) (6)	
User entered 'Mild (Mild)' reason for change: Data	(b) (4), (b) (6)	08 Dec 2020 13:28:17
Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 13:28:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:52:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 13:28:17
	(b) (4), (b) (6)	
User entered 'Mild (Mild)' reason for change: Data	(b) (4), (b) (6)	08 Dec 2020 13:28:17
Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:20:54
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 17:40:29
	(b) (4), (b) (6)	

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Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '26 Oct 2020'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '99'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
User entered '%'	(b) (4), (b) (6) System	08 Dec 2020 13:29:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:10
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '36.8' C	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:15
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:22
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:23
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:26
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'None (None)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:52:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Dec 2020 13:29:17
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:52:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 21:33:28

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the sample dated 26 OCT 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:22:50
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the sample dated 26 OCT 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 12:51:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:21:57
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:21:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:21:44
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the sample dated 26 OCT 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:38:13
User entered '26 Oct 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:52:05

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

[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 21:33:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:21:40
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:52:05

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

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 21:33:35
User closed query 'Is source available yet? ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 17:57:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:00:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
Query 'Is source available yet? ' answered with 'subject was negative for COVID' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 14:15:53
User opened query 'Is source available yet? ' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 18:44:23
	(b) (4), (b) (6)	
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 18:44:23
	(b) (4), (b) (6)	
Query 'Please provide source.' answered with 'unknown ' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 12:52:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 12:52:13
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 12:52:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	13 Nov 2020 12:52:07
User opened query 'Please provide source.' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 12:52:07
	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:21:25
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 12:52:05
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:21:26
User entered '26 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 12:52:05
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:21:28
User entered 'Nasal Swab (Nasal Swab)'	(b) (4), (b) (6)	27 Oct 2020 12:52:05
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:21:34
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 12:52:05
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

[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 21:33:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:21:31
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:52:05

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:21:35
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 12:52:05
	(b) (4), (b) (6)	

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:21:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 12:52:05

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:52:39

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:35
User entered '0'	(b) (4), (b) (6) System	27 Oct 2020 12:52:05

US3022065

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:52:39

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:33:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:22:53
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 12:52:10
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:52:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:52:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:52:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:52:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:52:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:52:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:52:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:52:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:52:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:52:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:52:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:52:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:52:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:52:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:52:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:52:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:52:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:52:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:52:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:52:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:52:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:49
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:22:19
	(b) (4), (b) (6)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:13
Query 'Per eCCGs, COVID-19 negative patients should be entered as unscheduled visits. Please remove visits from here, and please add in an unscheduled visit.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:50:21
User opened query 'Per eCCGs, COVID-19 negative patients should be entered as unscheduled visits. Please remove visits from here, and please add in an unscheduled visit.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:48:26
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 12:39:09
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:13
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 12:39:09
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[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 19:42:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:13
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4)	10 Nov 2020 12:39:09
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:32
User entered 'SICKD1'	(b) (4), (b) (6) System	10 Nov 2020 12:39:09

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '11:25'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User entered '26 Oct 2020 11:25'	(b) (4), (b) (6) System	10 Nov 2020 12:40:41

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '169' cm	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41
	(b) (4)	
DataPoint set to visible.	System	10 Nov 2020 12:39:09

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '93.7' kg	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41
	(b) (4)	
DataPoint set to visible.	System	10 Nov 2020 12:39:09

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '36.8' C	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '75'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User entered 'bpm'	(b) (4), (b) (6) System	10 Nov 2020 12:40:41

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '15'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User entered 'breaths/min'	(b) (4), (b) (6) System	10 Nov 2020 12:40:41

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '126'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User entered 'mmHg'	(b) (4), (b) (6) System	10 Nov 2020 12:40:41

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '87'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:41
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:37
User entered 'mmHg'	(b) (4), (b) (6) System	10 Nov 2020 12:40:41

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:42:37

US3022065

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:42:37

US3022065

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:41
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:55:34
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:50
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:41
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:55:34
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 12:40:50
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:52:39

[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 19:42:44
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:18
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 12:41:00
	(b) (4)	

US3022065

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:52:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:42:44
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:18
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 12:41:00
	(b) (4)	

US3022065

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

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:25:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:16:33
	(b) (4), (b) (6)	

US3022065

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

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:25:56
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:16:33

US3022065

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

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:26:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Jan 2021 16:16:33

US3022065

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

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 16:16:33

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:01
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '22 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:17:28
	(b) (4), (b) (6)	

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:45:27
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 12:37:16
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6) System	06 Mar 2021 10:44:06

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:17:28
	(b) (4), (b) (6)	

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
DataPoint Verified.	(b) (4)	12 Apr 2021 13:45:28
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:14:55
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:37:40
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 12:37:16
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:15:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:44:06

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:17:28

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:17:28

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:17:28

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:17:28

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:17:28
	(b) (4), (b) (6)	

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '1'	System	22 Jan 2021 16:17:28

US3022065

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'I'	System	22 Jan 2021 16:17:28

US3022065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered empty.	System	22 Jan 2021 16:18:57
DataPoint set to visible.	System	22 Jan 2021 16:17:28

US3022065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered empty.	System	22 Jan 2021 16:18:57
DataPoint set to visible.	System	22 Jan 2021 16:17:28

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:37:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:37:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '22 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:37:21
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '09:54'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '22 Jan 2021 09:54'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:37:23
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '37.0' C	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:37:25
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (Oral)'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:49:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:37:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '67'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'bpm'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:37:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '18'	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'breaths/min'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:37:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '122'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:37:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '72'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:36:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered empty.	System	22 Jan 2021 16:18:57
DataPoint set to visible.	System	22 Jan 2021 16:17:28

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:39:39
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:39:45
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:39:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '10:56'	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '22 Jan 2021 10:56'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:39:50
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '37.0' C	(b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:39:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (Oral)'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:50:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:40:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '68'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'bpm'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:40:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '16'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'breaths/min'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:40:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '136'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:40:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '84'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:18:57
	(b) (4), (b) (6)	

US3022065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	22 Jan 2021 16:18:57

US3022065

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:40:33
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:19:31
	(b) (4), (b) (6)	

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:40:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '22 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:19:31
	(b) (4), (b) (6)	

US3022065

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:40:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:19:54
	(b) (4), (b) (6)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:49:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:19:54
	(b) (4), (b) (6)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

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)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:19:54
	(b) (4), (b) (6)	

US3022065

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mRNA-1273'	System	22 Jan 2021 16:19:54
DataPoint set to visible.	System	22 Jan 2021 16:17:28

US3022065

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:40:57
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 16:19:54

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:41:01
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '10:26'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:19:54

US3022065

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '22 Jan 2021 10:26'	System	22 Jan 2021 16:19:54

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:41:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:19:54

US3022065

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:41:09
User entered 'ONCE'	System	22 Jan 2021 16:19:54

US3022065

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 16:19:54

US3022065

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:41:29
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:19:17

US3022065

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:41:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '22 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:19:17
	(b) (4), (b) (6)	

US3022065

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:41:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '09:20'	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:19:17
	(b) (4), (b) (6)	

US3022065

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '22 Jan 2021 09:20'	System	22 Jan 2021 16:19:17

US3022065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:41:45
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:19:25

US3022065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:52:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:41:47
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:19:25

US3022065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:52:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:41:49
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '09:24'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:19:25

US3022065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:52:39

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '22 Jan 2021 09:24'	System	22 Jan 2021 16:19:25

US3022065

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

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:42:06
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 16:20:03

US3022065

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

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'I'	System	22 Jan 2021 16:20:03

US3022065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:42:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:28:51

US3022065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:42:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '29 Jan 2021'	(b) (4), (b) (6)	19 Feb 2021 17:28:51

US3022065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:42:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Feb 2021 17:28:51

US3022065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:42:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:28:51

US3022065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:42:50
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:28:57

US3022065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'I'	System	19 Feb 2021 17:28:57

US3022065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '1'	System	19 Feb 2021 17:28:57
DataPoint set to visible.	System	19 Feb 2021 17:28:57

US3022065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:11
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:29:07

US3022065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:11
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '16 Feb 2021'	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 17:29:07
	(b) (4), (b) (6)	

US3022065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:11
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:29:07

US3022065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'OLD29'	System	19 Feb 2021 17:29:07

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 17:31:00
	(b) (4), (b) (6)	

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '16:14'	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '16 Feb 2021 16:14'	System	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '36.7' C	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '60'	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'bpm'	System	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '16'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'breaths/min'	System	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '135'	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 17:31:00
	(b) (4), (b) (6)	

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '73'	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '17:59'	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 17:31:00
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '16 Feb 2021 17:59'	System	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '36.9' C	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '64'	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'bpm'	System	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '16'	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'breaths/min'	System	19 Feb 2021 17:31:00

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '136'	(b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:49:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '86'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	19 Feb 2021 17:31:00

US3022065

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:50:31
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:29:19

US3022065

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:50:31
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '16 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 17:29:19

US3022065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:50:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 17:29:59
	(b) (4), (b) (6)	

US3022065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:50:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	19 Feb 2021 17:29:59

US3022065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

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)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:50:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:29:59

US3022065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mRNA-1273'	System	19 Feb 2021 17:29:59
DataPoint set to visible.	System	19 Feb 2021 17:28:57

US3022065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:50:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:29:59

US3022065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:50:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '17:29'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:29:59

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '16 Feb 2021 17:29'	System	19 Feb 2021 17:29:59

US3022065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:50:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:29:59

US3022065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:50:54
User entered 'ONCE'	System	19 Feb 2021 17:29:59

US3022065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 17:29:59

US3022065

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:52:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:29:25

US3022065

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'I'	System	19 Feb 2021 17:29:25

US3022065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:52:41
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:56:00
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 14:40:15
	(b) (4), (b) (6)	

US3022065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:52:41
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:56:00
User entered '23 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 14:40:15

US3022065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:52:41
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:56:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Feb 2021 14:40:15

US3022065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:52:41
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:56:00
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Feb 2021 14:40:15

US3022065

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:52:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:56:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 14:40:24

US3022065

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'I'	System	24 Feb 2021 14:40:24

US3022065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:08
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	23 Mar 2021 19:46:50

US3022065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:08
User entered '15 Mar 2021'	Chevon Roberts (b) (4)	23 Mar 2021 19:46:50

US3022065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:08
User entered 'Clinic (Clinic)'	Chevon Roberts (b) (4)	23 Mar 2021 19:46:50

US3022065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'OLD57'	System	23 Mar 2021 19:46:50

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered '15 Mar 2021'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered '09:20'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '15 Mar 2021 09:20'	System	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered '36.8' C	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered 'Oral (Oral)'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered empty.	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered '63'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'bpm'	System	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered '16'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'breaths/min'	System	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered '142'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:00:42
User entered '88'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered 'mmHg'	System	23 Mar 2021 19:47:32

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29

US3022065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29

US3022065

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:01:20
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:39

US3022065

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:01:20
User entered '15 Mar 2021'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:39

US3022065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:01:36
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:54

US3022065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:01:36
User entered '15 Mar 2021'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:54

US3022065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:01:36
User entered '09:37'	Chevon Roberts (b) (4)	23 Mar 2021 19:47:54

US3022065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:40:29
User entered '15 Mar 2021 09:37'	System	23 Mar 2021 19:47:54

US3022065

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:52:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:10:06
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	11 Nov 2020 18:45:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:45:28
User entered 'No (N)'	Shanice Bennett (b) (4)	01 Sep 2020 13:05:47

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:21:51

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:45:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:45:58
	(b) (4)	
Data point term sent to Coder	System	28 Oct 2020 17:46:54
User entered 'acute sinusitis'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '26 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
User entered empty.	(b) (4), (b) (6) System	28 Oct 2020 17:46:22

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:54:50
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Un-verified.	(b) (4)	
	Chevon Roberts (b) (4)	13 Nov 2020 19:49:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 19:49:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 12:44:57
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:05:14
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:54:56
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	Chevon Roberts (b) (4)	13 Nov 2020 19:49:25
	(b) (4)	
User entered '09 Nov 2020' reason for change: Data Entry Error	Chevon Roberts (b) (4)	13 Nov 2020 19:49:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 12:44:57
	(b) (4)	
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:05:14
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
User entered empty.	(b) (4), (b) (6) System	28 Oct 2020 17:46:22

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 17:46:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 17:46:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Oct 2020 17:46:40
reason for change: Data Entry Error	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 17:46:22
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:14:29
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. Kindly review and update this field as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:29:39
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. Kindly review and update this field as appropriate.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:49:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:49:48
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. Kindly review and update this field as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Nov 2020 15:31:14
User entered 'None (NONE)'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 17:46:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:59:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Un-verified.	(b) (4)	
	Chevon Roberts (b) (4)	13 Nov 2020 19:49:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Chevon Roberts (b) (4)	13 Nov 2020 19:49:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 12:44:57
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:05:14
	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

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 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:46:22
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
User entered '0'	(b) (4), (b) (6) System	28 Oct 2020 17:46:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:51
User entered '1'	(b) (4), (b) (6) System	28 Oct 2020 17:46:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:39

[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 08:21:51

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:21:46

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy cervical - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 16:54:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 16:54:44
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 13:30:59
User entered 'RIGHT ANTERIOR CERVICAL CHAIN LYMPHADENOPATHY'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 13:30:20

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	Chevon Roberts (b) (4)	13 Nov 2020 19:43:45
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Chevon Roberts (b) (4)	13 Nov 2020 19:43:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:00:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Un-verified.	Chevon Roberts (b) (4)	13 Nov 2020 19:43:45
	(b) (4)	
User entered '09 Nov 2020' reason for change: Data Entry Error	Chevon Roberts (b) (4)	13 Nov 2020 19:43:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 13:30:20

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Folder: Adverse Events

Form: Adverse Events (6)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

US3022065

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

US3022065

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

US3022065

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

US3022065

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Not Applicable (NOT APPLICABLE)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'I'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:00:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Un-verified.	(b) (4)	
	Chevon Roberts (b) (4)	13 Nov 2020 19:43:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Chevon Roberts (b) (4)	13 Nov 2020 19:43:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

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 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

US3022065

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:14:29
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 13:30:20
	(b) (4)	

US3022065

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
User entered '0'	(b) (4), (b) (6) System	10 Nov 2020 13:30:20

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:21:46
User entered '0'	(b) (4), (b) (6) System	10 Nov 2020 13:30:20

US3022065

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:52:39

[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 08:21:46

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
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) (4), (b) (6) (b) (4), (b) (6)	05 Jan 2021 06:58:10
Query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term ' answered with 'no other diagnosis ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	30 Dec 2020 13:35:54
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 11:25:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	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 21:05:51
User entered 'possible covid infection'	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 21:05:29

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '22 Oct 2020'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:05:29

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	07 Dec 2020 21:05:43
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	07 Dec 2020 21:05:43
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	07 Dec 2020 21:05:29
User entered '09 Nov 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 21:05:29

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:05:29

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	07 Dec 2020 21:05:43
Data Entry Error	(b) (4), (b) (6)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	07 Dec 2020 21:05:29

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:01:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 21:05:29
	(b) (4), (b) (6)	

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 21:05:29

US3022065

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:52:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 21:05:29

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:52:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:10:06
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 18:46:26
	(b) (4), (b) (6)	
User closed query 'Please add Acetaminophen, Dextromethorphan, and Guaifenesin.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 16:56:33
	(b) (4), (b) (6)	
Query 'Please add Acetaminophen, Dextromethorphan, and Guaifenesin.' answered with 'ADDED. COMBINATION MED' (Site from CRA).	Chevon Roberts (b) (4)	13 Nov 2020 19:51:07
	(b) (4)	
User opened query 'Please add Acetaminophen, Dextromethorphan, and Guaifenesin.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:53:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 12:42:40
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	01 Sep 2020 13:05:51
	(b) (4)	

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:04:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 12:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 12:44:49
Data point term sent to Coder User entered 'losartan'	System (b) (4), (b) (6)	01 Oct 2020 12:44:05
	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:05:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:05:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'hypertension'	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 16:50:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:05:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered '50'	(b) (4), (b) (6)	01 Oct 2020 12:43:25
	(b) (4), (b) (6)	

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:05:25
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
Signature has been broken.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:51:18
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:05:29
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:05:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 16:51:04
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:05:47
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:43:25
	(b) (4), (b) (6)	

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:05:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:05:59
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'un UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 12:43:25

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: INDAPAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Oct 2020 22:46:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 22:46:58
Data point term sent to Coder	System	01 Oct 2020 12:45:07
User entered 'indapomide'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:28
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'hypertension'	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '1.25'	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:45
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:47
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:50
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:06:56
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:07:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:07:06
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'un UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:07:11
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
User closed query 'Per source this is not ongoing. Please update.' (Site from CRA).	(b) (4)	07 Apr 2021 17:44:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:57:52
	(b) (4), (b) (6)	
Query 'Per source this is not ongoing. Please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 16:43:06
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 16:42:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 16:42:42
User opened query 'Per source this is not ongoing. Please update.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 21:07:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4)	01 Oct 2020 12:44:10
	(b) (4), (b) (6)	

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:48
User closed query 'Per Source end date is Un Nov 2020. Please update.' (Site from CRA).	(b) (4)	07 Apr 2021 17:44:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:57:53
	(b) (4), (b) (6)	
Query 'Per Source end date is Un Nov 2020. Please update.' answered with 'updated ' (Site from CRA). Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 16:43:21
	(b) (4), (b) (6)	01 Apr 2021 16:42:42
User entered 'un Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 16:42:42
User opened query 'Per Source end date is Un Nov 2020. Please update.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 21:08:37
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 21:07:55
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:07:50
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4)	01 Oct 2020 12:44:10
	(b) (4), (b) (6)	

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:07:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
User entered '1'	System	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
User entered '1'	System	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:12:08
User entered '804 (804)'	System	01 Oct 2020 12:44:10

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:08:47
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 23:18:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 23:18:54
Data point term sent to Coder	System	01 Oct 2020 12:45:05
User entered 'omeprazole'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:09:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'gastroesophageal reflux diseases'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:09:55
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '20'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 21:09:57
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:31:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:31:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:31:49
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:31:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:31:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:31:57
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'un UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:31:59
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:32:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:32:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:32:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 12:45:02

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:42:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:01:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:01:46
Data point term sent to Coder	System	28 Oct 2020 17:45:53
User entered 'sulfamethoxazole/trimethoprim'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:42:25
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:42:28
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'acute sinusitis'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:42:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '800/160'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:42:39
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:42:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:42:57
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:42:59
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:43:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:43:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:43:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '26 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:43:39
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:43:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User closed query 'Per ConMed Log, this is discrepant. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 18:48:01
User closed query 'Per DM CLR-REQUERY: Response noted, however, please note that if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 14:42:32
Query 'Per DM CLR-REQUERY: Response noted, however, please note that if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:02:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 16:02:38
User opened query 'Per DM CLR-REQUERY: Response noted, however, please note that if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 03:07:44
Query 'Per ConMed Log, this is discrepant. Please confirm and update if needed.' answered with 'upsated' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 12:41:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 12:41:06
User opened query 'Per ConMed Log, this is discrepant. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:47:50
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:43:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 16:02:38
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	13 Nov 2020 12:41:06
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	28 Oct 2020 17:45:03
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:43:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
User entered '2'	System	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
User entered '1'	System	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:13:01
User entered '804 (804)'	System	28 Oct 2020 17:45:03

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:58:17
	(b) (4), (b) (6)	
Query 'Per source name of medication is Acetaminophen, Detromethorplan, Guaifenesin. Please verify and update.' canceled (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 13:01:29
User opened query 'Per source name of medication is Acetaminophen, Detromethorplan, Guaifenesin. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 12:53:59
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please review if this combination drug includes four active ingredients. If so, please update Medication Name to reflect the complete name/ingredients of the medication, as well as the dose in the dose field as appropriate. Update eCRF as appropriate.	(b) (4), (b) (6)	16 Feb 2021 02:16:51
' (Site from DM).		
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)	29 Jan 2021 17:41:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	29 Jan 2021 17:41:22
Query 'Per DM CLR: The medication cannot be verified as entered. Please review if this combination drug includes four active ingredients. If so, please update Medication Name to reflect the complete name/ingredients of the medication, as well as the dose in the dose field as appropriate. Update eCRF as appropriate.	System	29 Jan 2021 17:40:37
' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 17:40:08
Coding entries removed.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	29 Jan 2021 17:40:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

Name of Medication

Audit	User	Time (GMT)
User entered 'ACETAMINOPHEN' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 17:40:02
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please review if this combination drug includes four active ingredients. If so, please update Medication Name to reflect the complete name/ingredients of the medication, as well as the dose in the dose field as appropriate. Update eCRF as appropriate.	(b) (4), (b) (6)	29 Jan 2021 06:47:02
' (Site from DM).		
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 14:34:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	08 Dec 2020 14:34:55
Data point term sent to Coder	System	07 Dec 2020 21:07:54
Coding entries removed.	(b) (4), (b) (6)	07 Dec 2020 21:07:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 22:14:53
Data point term sent to Coder	(b) (4)	
User entered	Coder Import (b) (4)	14 Nov 2020 22:14:53
'ACETAMINOPHEN/DETROMETHORPLAN/GU AIFENESIN'	System	13 Nov 2020 19:54:45
	Chevon Roberts (b) (4)	13 Nov 2020 19:53:52
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:54:08
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
User closed query 'Per source indication is listed as cough muscle aches all over. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:46:09
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:58:27
	(b) (4), (b) (6)	
Query 'Per source indication is listed as cough muscle aches all over. Please verify and update.' answered with 'this is correct' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 16:45:26
User opened query 'Per source indication is listed as cough muscle aches all over. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 12:54:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'POSSIBLE COVID INFECTION' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 21:07:38
User entered 'COUGH/ MUSCLE ACHES'	Chevon Roberts (b) (4)	13 Nov 2020 19:53:52
	(b) (4)	

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:58:47
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please provide the single dose for the medication - acetaminophen per update. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 13:07:21
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:25
Query 'Per DM CLR: Please provide the single dose for the medication - acetaminophen per update. Review and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:26:25
User entered '325' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:26:17
User opened query 'Per DM CLR: Please provide the single dose for the medication - acetaminophen per update. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 02:17:58
User entered '325/10/200'	Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 19:53:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:58:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	13 Nov 2020 19:53:52
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:48:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	13 Nov 2020 19:53:52
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:58:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'other (OTHER)'	(b) (4)	
	Chevon Roberts (b) (4)	13 Nov 2020 19:53:52
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:09:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'EVERY 4 HOURS'	(b) (4) Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:09:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (ORAL)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:09:20
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) Chevon Roberts (b) (4)	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:09:08
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '24 Oct 2020'	(b) (4) Chevon Roberts (b) (4)	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:09:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	(b) (4) Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:09:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:09:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '25 Oct 2020'	(b) (4) Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 19:53:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:09:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
User entered empty.	System	13 Nov 2020 19:53:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
User entered empty.	System	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:04
User entered empty.	System	13 Nov 2020 19:53:52

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:13:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Dec 2020 18:54:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Dec 2020 18:54:27
Data point term sent to Coder	System	07 Dec 2020 21:06:52
Coding entries removed.	(b) (4), (b) (6)	07 Dec 2020 21:06:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\202003.	(b) (4), (b) (6) Coder Import (b) (4)	19 Nov 2020 21:22:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 21:22:13
Data point term sent to Coder	System	19 Nov 2020 21:06:34
User entered 'benzonatate'	Shanice Bennett (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:13:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:13:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'possible covid infection' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 21:06:21
User entered 'cough'	Shanice Bennett (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:13:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '100'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:13:55
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'mg (mg)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:13:57
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:13:59
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'as needed (PRN)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:01
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (ORAL)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:07
User closed query 'Per DM CLR RQ: Per response , however for CM # 4 and CM # 9 the indication and the start date is similar, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 01:09:07
Query 'Per DM CLR RQ: Per response , however for CM # 4 and CM # 9 the indication and the start date is similar, kindly review and amend as appropriate.' answered with 'That is correct. 4 different medications were taken for the same thing, at the same time.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 13:50:35
User opened query 'Per DM CLR RQ: Per response , however for CM # 4 and CM # 9 the indication and the start date is similar, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:39:07
User closed query 'Per CDM, DM CLR re-query: Response "will update" is noted; however no update has been made. Please review if this entry is a duplicate with CM#4 or update the dates as necessary. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:39:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
Query 'Per CDM, DM CLR re-query: Response "will update" is noted; however no update has been made. Please review if this entry is a duplicate with CM#4 or update the dates as necessary. Review and update as appropriate. ' answered with 'thisis not a duplicate' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:27:14
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM#4 (26 OCT 2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Feb 2021 08:28:43

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM, DM CLR re-query: Response "will update" is noted; however no update has been made. Please review if this entry is a duplicate with CM#4 or update the dates as necessary. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:27:56
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM#4 (26 OCT 2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	29 Jan 2021 17:46:02
' answered with 'will update' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 06:41:44
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM#4 (26 OCT 2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	Shanice Bennett (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '09 Nov 2020'	Shanice Bennett (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:21
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
User entered empty.	System	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
User entered empty.	System	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:06
User entered empty.	System	19 Nov 2020 21:05:47

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Feb 2021 17:05:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Feb 2021 17:05:54
Data point term sent to Coder	System	19 Feb 2021 17:28:24
Coding entries removed.	(b) (4), (b) (6)	19 Feb 2021 17:27:51
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 18:52:20
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:52:16
	(b) (4), (b) (6)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 03:49:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 03:49:53
Data point term sent to Coder	System	19 Nov 2020 21:07:36

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'albuterol inhaled'	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'possible covid-19 infection' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:27:51
User entered 'cough/ shortness of breath'	Shanice Bennett (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '90'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:47
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:04:07
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 12:58:06
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 17:47:32
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 17:47:14
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 06:53:27
User entered 'IU (IU)'	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User closed query 'Per CDM: Please note that ug (for microgram) is one of the available options from the drop-down list provided for Dose unit. Kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 06:23:35
Query 'Per CDM: Please note that ug (for microgram) is one of the available options from the drop-down list provided for Dose unit. Kindly review and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 16:04:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 16:04:07
User opened query 'Per CDM: Please note that ug (for microgram) is one of the available options from the drop-down list provided for Dose unit. Kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:58:04
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 17:47:14
User entered empty.	Shanice Bennett (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'as needed (PRN)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:14:57
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:04
User closed query 'Per DM CLR RQ: Per response , however for CM # 5 and CM # 10 the indication and the start date is similar, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 01:09:31
Query 'Per DM CLR RQ: Per response , however for CM # 5 and CM # 10 the indication and the start date is similar, kindly review and amend as appropriate.' answered with 'That is correct. 4 different medications were taken for the same thing, at the same time.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 13:50:43
User opened query 'Per DM CLR RQ: Per response , however for CM # 5 and CM # 10 the indication and the start date is similar, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:41:13
User closed query 'Per CDM, DM CLR re-query: Response "will update" is noted; however no update has been made. Please review if this entry is a duplicate with CM#5 or update the dates as necessary. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:41:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
Query 'Per CDM, DM CLR re-query: Response "will update" is noted; however no update has been made. Please review if this entry is a duplicate with CM#5 or update the dates as necessary. Review and update as appropriate. ' answered with 'this is not a duplicate' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:28:02
User opened query 'Per CDM, DM CLR re-query: Response "will update" is noted; however no update has been made. Please review if this entry is a duplicate with CM#5 or update the dates as necessary. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Feb 2021 08:30:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM#5 (26 OCT 2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Feb 2021 08:30:15
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM#5 (26 OCT 2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'will update' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 17:47:45
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM#5 (26 OCT 2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 06:53:21
User entered '26 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	Shanice Bennett (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '09 Nov 2020'	Shanice Bennett (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	Shanice Bennett (b) (4)	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
User entered empty.	System	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
User entered empty.	System	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:09
User entered empty.	System	19 Nov 2020 21:06:38

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:01:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:01:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:25
Data point term sent to Coder	System	19 Feb 2021 17:28:24
Coding entries removed.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:28:21
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:40:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:40:55
Data point term sent to Coder	System	19 Nov 2020 21:07:37
User entered 'methyl prednisone'	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'possible covid-19 infection' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:28:21
User entered 'acute sinusitis'	Shanice Bennett (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '4'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:49
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'mg (mg)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:50
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'other (OTHER)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:54
User closed query 'Per CDM: Please review if the Frequency can be selected from one of the available options from the drop-down list provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:57:28
Query 'Per CDM: Please review if the Frequency can be selected from one of the available options from the drop-down list provided. Thank you. ' answered with 'THIS IS CORRECT' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 19:50:52
User opened query 'Per CDM: Please review if the Frequency can be selected from one of the available options from the drop-down list provided. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 08:03:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:25
User entered 'as directed'	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'Oral (ORAL)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:15:59
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:16:02
User closed query 'Per DM CLR RQ: Per response , however for CM # 6 and CM # 11 the indication and the start date is similar, kindly review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:36:48
Query 'Per DM CLR RQ: Per response , however for CM # 6 and CM # 11 the indication and the start date is similar, kindly review and amend as appropriate. ' answered with 'That is correct. 4 different medications were taken for the same thing, at the same time.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 13:50:50
User opened query 'Per DM CLR RQ: Per response , however for CM # 6 and CM # 11 the indication and the start date is similar, kindly review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:41:45
User closed query 'Per CDM, DM CLR re-query: Response "will update" is noted; however no update has been made. Please review if this entry is a duplicate with CM#6 or update the dates as necessary. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:41:45
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
Query 'Per CDM, DM CLR re-query: Response "will update" is noted; however no update has been made. Please review if this entry is a duplicate with CM#6 or update the dates as necessary. Review and update as appropriate. ' answered with 'this is not a duplicae' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:28:33
User opened query 'Per CDM, DM CLR re-query: Response "will update" is noted; however no update has been made. Please review if this entry is a duplicate with CM#6 or update the dates as necessary. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Feb 2021 08:31:32

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 6 (26 OCT 2020 - 09 NOV 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Feb 2021 08:31:09
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 6 (26 OCT 2020 - 09 NOV 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 17:48:07
' answered with 'will update' (Site from DM).		
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 6 (26 OCT 2020 - 09 NOV 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	29 Jan 2021 06:47:40
' (Site from DM).		
User entered '26 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:16:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '0'	Shanice Bennett (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:16:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:16:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered '09 Nov 2020'	Shanice Bennett (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:16:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
User entered 'No (N)'	Shanice Bennett (b) (4)	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
User entered empty.	System	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
User entered empty.	System	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:42:12
User entered empty.	System	19 Nov 2020 21:07:31

US3022065

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:52:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:19:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:41:04
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:40:48
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	01 Sep 2020 13:05:56
	(b) (4)	